The new rules wipe out such staples of tobacco marketing as free samples, colorful billboards and cigarette brand advertising at sporting events. They ban vending machines except in "adult" facilities where children are not allowed, and eliminate slick, color cigarette ads in magazines read by significant numbers of teens.

In announcing the regulations, the President assailed tobacco advertising for leading the nation's youth into nicotine addiction. "With this historic action we are taking today," he said, "Joe Camel and the Marlboro Man will be out of our children's reach forever!"

Since the draft regulations were published a year ago, the government has received more than 95,000 different comments in more than 700,000 pieces of mail. The tobacco industry filed suit in North Carolina to block the plan as soon as the proposed rules were announced, and has heavily lobbied the Congress and the White House to defeat or soften the rules. To counter those efforts, ASAM worked with the AMA and other health and consumer protection organizations to move the proposed regulations forward essentially intact (see page 4 for ASAM's letter to President Clinton).

In implementing the rules, the FDA will require six companies that it says have attracted the largest percentages of underaged consumers to run a campaign—including television spots—that will warn children and adolescents about the dangers of tobacco. The six companies that are required to develop the campaign (which will be monitored by the FDA) are cigarette makers Phillip Morris, RJR Nabisco and Lorillard Tobacco, and smokeless tobacco producers United States' Tobacco, Pinkerton Tobacco and Conwood Tobacco. Phillip Morris' Marlboro cigarettes, RJR's Camel brand and Lorillard's Newport are the most popular brands of cigarettes among young people, according to the FDA.

The biggest changes in advertising will be in billboard displays, publications targeted at youth audiences and sporting events such as NASCAR racing's Winston Cup series. Billboards will be allowed to carry tobacco advertising only in black and white text and no billboards advertising tobacco will be allowed within 1,000 feet of a school or playground. Advertising in stores and other establishments will be limited to black-and-white text, except in "adult only" facilities. Publications targeted at young readers—including national magazines such as Rolling Stone and Sports Illustrated—will be limited to carrying black-and-white, text-only advertising for tobacco products. (Publications with readerships that are 85 percent or more adults, including periodicals like Time and Newsweek, do not fall under the advertising restrictions.)

President Clinton: "With this historic action..., Joe Camel and the Marlboro Man will be out of our children's reach forever!"

Sporting events could be sponsored by corporations that produce cigarettes and other tobacco products, and player uniforms and race cars could be adorned with corporate logos, but not with product brands. For example, a racing team might be sponsored by United States' Tobacco, but it could not carry advertising for the company's Skoal brand of smokeless tobacco.

Also, purchasers of tobacco products who are under 27 years of age will be required to prove their age with photo identification cards. The ID rule will take effect in six months, while the other rules become effective a year from publication. The ban on tobacco brand sponsorship of sporting, music...
EXECUTIVE VICE PRESIDENT'S REPORT

ASAM WORKS TO INCREASE ACCESS, QUALITY OF CARE

Two strategic goals that ASAM vigorously pursues in collaboration with our state chapters are to increase access to care and the quality of care, and to increase recognition of addiction medicine by organized medicine and public policy makers.

With the publication of the ASAM Patient Placement Criteria, Second Edition (ASAM PPC-2), through the efforts of the working group on the ASAM PPC-2 (David Mee-Lee, M.D., Chairperson and Lee Gartner; Michael M. Miller, M.D.; Gerald D. Shulman, M.A.; FACATA, Vice-Chairperson; Bonnie B. Wilford, M.S., Managing Editor), ASAM has greatly advanced our efforts to assure access to care and quality of care.

ASAM PPC-2 is gaining increasing acceptance and use in the public sector and is showing signs of potentially more widespread use in the private sector. The National Association of State Alcohol and Drug Abuse Directors (NASADAD) has, through the efforts of Julian Keith, M.D., (NASADAD Board member and Director of the North Carolina Division of Substance Abuse Services), officially endorsed the Criteria and recommended their adoption by the state directors throughout the country. Two states, Illinois and Iowa, have already required their use for all addiction services provided within the state. In both states, the ASAM chapter presidents (Dennis Weiss, M.D., Iowa; Martin C. Doot, M.D., Illinois) and chapter members were instrumental in the states' decisions to use the Patient Placement Criteria.

All state directors have received a copy of the Criteria, and state chapter presidents and state chairs are urged to meet with the state directors to offer consultation. Dr. Doot (847-698-4775) has agreed to speak with chapter presidents interested in learning more about the consulting contract the Illinois chapter has established with the state. The South Carolina and Georgia chapters recently held statewide conferences at which David Mee-Lee, M.D. provided training on use of the Criteria.

In the private sector, the American Managed Behavioral Healthcare Association (AMBHA) and its member organizations have expressed interest in the ASAM PPC-2, and representatives of AMBHA and ASAM will meet to discuss managed care's use of the Criteria. In addition, an informal coalition of managed care organization medical directors (Managed Care Coalition on Substance Use Disorders [MCCSU], hosted by ASAM (Michael M. Miller, M.D., Chair) has met in person and through conference calls over the past two years to discuss areas of mutual concern regarding treatment placement, continued stay and discharge criteria, and treatment costs and quality assurance.

In addition to continuing the AMBHA and MCCSU dialogue, ASAM will host the fifth annual meeting of the National Coalition for Clinical Criteria, November 13, in Washington, D.C. as a venue for representatives of providers, professional associations, third party payers, managed care organizations, corporations and government, who have agreed to work together toward the development of a national consensus on criteria. The group will discuss implementation of the ASAM PPC-2 and the proposed 1997 updates, and the hypertext and algorithmic software versions under development.

Continued on next page
President Signs Bill Expanding Coverage for Mental Illnesses

President Clinton in September signed into law a long-sought bill prohibiting health insurance plans from establishing more restrictive lifetime or annual limits on coverage of mental illnesses than they do for physical ailments. However, attempts to persuade lawmakers to include coverage of alcohol and drug treatment failed.

The fight for greater equity in treatment of mental illnesses was long and hard. Bill sponsor Sen. Pete Domenici (R-NM), who has been fighting for equity for more than a decade, said it is common for health plans to limit lifetime mental coverage to $50,000 while allowing up to $1 million for physical illnesses.

Business and managed care groups claimed that, based on the experience of plans in states where legislators have mandated similar benefits, the mental health provisions will cause premium costs to rise 4 to 7 percent annually. On the other hand, a study by the accounting firm Coopers & Lybrand for the American Psychological Association placed the cost of adding such a benefit at only 0.12 percent more, or 17 cents per member per month.

The new provisions do not require insurers to offer mental health coverage, but require them to impose equivalent lifetime and annual limits if they do. Small businesses with 50 or fewer employees are exempted, and the date of implementation was put off until Jan. 1, 1998. The new law also contains a provision that a health plan that can show its costs rose 1 percent because of the expanded mental health coverage can be exempted from providing the coverage.

Caribbean Trafficking is Key to U.S. Drug Trade

The islands of the eastern Caribbean have once again become a key transit zone for cocaine and heroin headed to the U.S., according to a recently declassified overview of the U.S. State Department. Gen. Barry McCaffrey, Director of the Office of National Drug Control Policy, said his office estimates that through 154 metric tons of cocaine pass through the eastern Caribbean to the U.S. each year, with another 180 metric tons moving through the way to Europe and Russia.

"The Caribbean is a significant drug transit zone because there are lots of harbors, lots of airstrips and governments without a lot of money," said Jonathan Winer, deputy assistant Secretary of State for law enforcement and crime. Traffickers have increased their activities in Puerto Rico. A particular target of the traffickers is Puerto Rico, from which drugs can be shipped anywhere in the U.S. without passing through Customs. James Milford, a Drug Enforcement Administration special agent in charge of the Miami field office, said that, because of the volume of air and sea commerce between Puerto Rico and the mainland U.S., "if you can get the drugs into Puerto Rico, you can get them into Iowa."

Political Rhetoric Overlooks Change in Drug-Use Patterns

While the Presidential candidates are promising swift action against adolescent drug use, law enforcement officials and epidemiologists warn that the new pattern of drug activity isn't susceptible to the same types of government initiatives used in the past. Unlike the drug epidemic of the late 1960s and early 1970s, the current trend involves early adolescents, often still in elementary school, rather than older teens in high school and college, whose drug of choice is marijuana. Moreover, because much of the marijuana supply comes from domestic growers and is believed to be distributed by small networks or individuals, law enforcement officials say that curtailing the supply will require a different approach than was used against cocaine and heroin—drugs that come entirely from abroad and that usually are distributed by large criminal organizations.

"The debate between prevention and punishment is a dead end," Patrick McGowan, sheriff of Hennepin County, Minnesota, told the Washington Post. "It is not an either/or choice. Education is essential for the long term when you are trying to keep 13-year-olds from making their first mistake, but in the short term there have to be meaningful consequences when people want to pollute our young with marijuana. Right now we are not doing a good job either way."

In the course of our conversation, General McCaffrey agreed to collaborate with ASAM in the following ways: (1) General McCaffrey will serve as keynote speaker at ASAM's 28th Annual Medical-Scientific Awards Dinner (April 19, 1997, San Diego); (2) he will provide ASAM with a transcribed text of his speech to the June 1996 meeting of the AMA House of Delegates (see ASAM News, July-August, 1996, Vol. 11, No. 3), which ASAM will send to each member of the AMA House of Delegates with a cover letter from Drs. Michael Miller, AMA Delegate, and David E. Smith, AMA Alternate Delegate; (3) he will distribute to his staff a "gold-standard" reading list on the addictions, to be compiled by ASAM; (4) he will invite ASAM to prepare a seminar for his staff on the field of addiction prevention, research and treatment; and (5) he has invited ASAM members to serve as scientific advisors to his office. General McCaffrey also encouraged ASAM to complete its national effort to develop chapters in each state, and offered to include in his speeches as he travelled throughout the country recommendations that physicians and others seek the assistance of ASAM members in the state. As a follow-up to this offer, he recently called the ASAM headquarters to request a roster of names, addresses and phone numbers of state chapter presidents. Following our visit to his office, General McCaffrey visited Dr. Smith's Haight-Ashbury Free Clinic while on a trip to San Francisco.

Through its efforts at the national and state levels, ASAM will continue to vigorously seek ways to assure access to care and quality of addiction medicine care, and to promote recognition of addiction medicine by the medical profession and by public policy makers. Recognition also includes attainment of specialty status, a matter that was discussed in depth at the October 1996 Board meeting in Seattle. A report of the Board's discussion and subsequent plans to attain ABMS recognition will appear in the next issue of ASAM News.
FROM THE PRESIDENT

Dear Colleague:

At every step along the way, ASAM vigorously supported President Clinton’s decision to curtail tobacco advertising practices that appeal to children and youth. An example is the following letter (drafted with the assistance of John Slade, M.D.) in which ASAM urged President Clinton to reject last-ditch efforts by the tobacco industry to escape much-needed federal regulation.

Dear President Clinton:

ASAM has been and remains a strong supporter of your proposal to regulate cigarettes and smokeless tobacco products that contain nicotine. Last week’s offer by Philip Morris and U.S. Tobacco, seeking a Congressionally mandated system for tobacco products, demonstrates the weakness of the industry’s position and the strength of your own. I write to urge your continued advocacy for the entire proposal that has been so carefully crafted by your Food and Drug Administration...

The offer itself is crafted to leave untouched huge expanses of tobacco product advertising that now reaches and appeals to the young. Moreover, the remaining means for marketing would be flexible enough to permit substantial expansion of their advertising efforts in remaining avenues. Such adaptation to changing rules has been the industry’s hallmark here and abroad for decades. When the industry controls the way the rules are set, it has never been unable to reach the young with its advertising. This is, simply, a Fox and Henhouse game.

Apart from the self-serving details, the Philip Morris/UST proposal has two fundamental structural defects which would make enactment of this in any form a public health disaster.

The proposal sets no target, no goal, for reducing tobacco use by minors. There is no yardstick by which to measure success. The only hint of this is the setting up of a Commission, but the Commission is given neither a specific charge nor any power to make changes. In contrast, the FDA proposal contains a very clear yardstick: has tobacco use by the young been cut in half? It is all very well and good for tobacco companies to pretend that they do not want the young to use their products, but until they, too, set measurable goals, their sincerity cannot be believed. Moreover, under the FDA proposal, that agency can make changes in its regulations as need and experience dictate.

The proposal uses the Congress as a regulatory agency. While several different executive agencies would have enforcement authority, these agencies would have no ability to change the rules even slightly if they were found to be ineffective. (But, of course, without a specific goal, effectiveness could not be officially measured in any case.) No other good or service enjoys regulation by Congress. Banking, securities, insurance, building trades, transportation, as well as food and drugs are a partial list of economic activities which are regulated by executive agencies at the federal and state levels to protect the public welfare.

Why is tobacco different? Why should it continue to get special treatment? If Congress continues to be the industry regulator (as has been the case since 1965), millions more will needlessly become addicted, get sick and die... If we take the easy way out on this and knowingly compromise away key provisions of what the FDA is trying to do, we will have become knowing partners in advancing the industry’s lies. The result is that the public will suffer for many, many years to come.

On the other hand, if you succeed in creating a genuine regulatory structure for tobacco products, one which is actually capable of achieving its goals, you will have made a major contribution to the health and prosperity of the United States and the rest of the world. ASAM stands by the FDA proposal and remains ready to help you shape policy which benefits the American people.

Peace and Health,

David E. Smith, M.D.
President

Save These Dates!

ASAM’S Review Course in Addiction Medicine
October 24-26, 1996  Chicago, IL

ASAM’S 9th National Conference on Nicotine Dependence
November 14-17, 1996  Washington, DC

For Complete Meeting Information
Call: 301.656.3920 or E-mail: asamoffice@aol.com
ASAM 9TH NATIONAL CONFERENCE ON NICOTINE DEPENDENCE TO MARK RECENT GAINS IN POLICY AND CLINICAL RESEARCH

Washington, D.C., is the site of ASAM's 9th National Conference on Nicotine Dependence, scheduled for November 14-17 at the ANA Hotel. The program committee, chaired by Andrea Barthwell, M.D., has organized the conference around four themes: (1) Nicotine and smoking through the life cycle; (2) a Food and Drug Administration update; (3) Nicotine use as a serious life problem, with past, present and future perspectives on the cultures that promote nicotine use; and (4) the smoking cessation guidelines developed by the federal Agency for Health Care Policy and Research.

The program committee—whose members include Drs. John Slade, Jack Henningfield, John Hughes, Richard Hurt, Lori Karan, Mark Robinson, John Rosecrans and Terry Rustin, and Mr. Gil Hill—also has planned preconference workshops on Thursday, November 14, sponsored by the Society on Research on Nicotine, as well as a Tobacco Research Roundtable on Neuroendocrine and Immune Effects of Nicotine sponsored by the National Institute on Drug Abuse. Also offered are two skill-building sessions, one on Practice Guidelines for Clinicians Treating Nicotine Dependence (organized by staff of the Mayo Clinic Nicotine Dependence Center), and the other on Treating Nicotine Dependence in the Treatment of Other Addictions, organized by John Slade, M.D. The first workshop focuses on practice guidelines in specific nicotine dependence settings, while the latter focuses on nicotine work within the context of general addiction treatment settings.

Throughout the conference, which is to be chaired by Andrea Barthwell, M.D., morning plenary sessions will provide a body of general information, while afternoon workshops offer an opportunity for a more detailed exchange of information on specific topics.

Friday, November 15
The morning plenary on "Nicotine and Smoking through the Life Cycle" (organized by Jack Henningfield, Ph.D.) includes presentations on Preteen Interventions, Nicotine Receptors in Adolescents, Nicotine in Pregnancy, and Medication Development for Use in Adults.

The keynote speaker at the conference lunch is Mitch Zeller, Deputy Associate Commissioner of the U.S. Food and Drug Administration. The luncheon will be followed by a response panel discussing FDA's actions, a poster session of accepted abstracts, and presentation of the Young Investigator Award.

Saturday, November 16

To register for the ASAM 9th National Nicotine Conference, contact the ASAM Meetings Department by phone at 301/656-3920; by fax at 301/656-3815; or by e-mail at ASAMOFFICE@AOL.COM.

Sunday, November 17
The morning plenary features a panel discussion of the AHCPR Smoking Cessation Guidelines, followed by a commentary, "Making It Work in Clinics, Hospitals and HMOs."

ASAM has designated the conference for 17.5 hours of Category 1 credit of the Physician's Recognition Award of the American Medical Association. ASAM has applied for approval of 17.5 hours of credits in Category 2-A of the American Osteopathic Association. The conference has been approved for 17.5 Continuing Education Credits of the American Psychological Association, and for 17.5 credit hours by the Cambridge Institute (for registered nurses, clinical social workers and certified addiction counselors). ASAM also has been approved as an education provider (#152) of the National Association of Alcohol and Drug Abuse Counselors.

Organizations cooperating to sponsor the conference include the American Academy of Pediatrics, the American Medical Association, the American Psychological Association, the American Public Health Association, the Centers for Disease Control and Prevention, the National Cancer Institute, and the National Institute on Drug Abuse. Program contributors include CIBA-Geigy, Glaxo-Wellcome, Hoechst Marion Roussel, McNeil Consumer Products Co., the National Institute on Drug Abuse, and SmithKline Beecham Consumer Healthcare.

Registration for the full conference is $325 for ASAM members and $375 for non-member physicians (one-day registrations can be provided on request to the ASAM meetings department). The conference fee includes conference registration, conference materials, the Saturday afternoon workshops, daily continental breakfasts, morning and afternoon refreshment breaks, lunch and a light evening reception on Friday, November 15, and lunch on Saturday, November 16. There is a separate $85 registration fee for each of the preconference workshops.

The ANA Hotel is located in Washington, D.C.'s fashionable West End, at the gateway to Georgetown and within minutes of the Kennedy Center. The hotel location affords easy access to the White House, Capitol and the city's other major attractions, including the Smithsonian museums and monuments, dining and theater. A special rate of $140 per night (single or double) is available to attendees; simply mention that you are attending the ASAM 9th National Nicotine Conference when making reservations. Reservations can be made by dialing 1-800-ANA-HOTEL or 202/429-2400.

ASAM Policy on Nicotine

ASAM advocates and supports the development of policies and programs that promote the prevention and treatment of nicotine use and addiction, such as the Food and Drug Administration's proposed regulations of tobacco products, and the federal Agency for Health Care Policy and Research's Clinical Practice Guideline on Smoking Cessation.

Through the work of its Committee on Nicotine Dependence and its Annual Conference on Nicotine Dependence, ASAM is committed to educating the public and the medical community about the harmful effects of tobacco use on smokers and nonsmokers alike.
FOCUS ON...NICOTINE DEPENDENCE

A BRIEF OVERVIEW: MANAGEMENT OF NICOTINE DEPENDENCE AND WITHDRAWAL

Robert M. Keenan, M.D., Ph.D.
Murray E. Jarvik, M.D., Ph.D.
Jack E. Henningfield, Ph.D.


Tobacco addiction involves two clinical disorders: (1) nicotine dependence, which derives from the reinforcing effects of nicotine, and (2) nicotine withdrawal, which accompanies nicotine abstinence in the daily tobacco user. Pharmacologic approaches can address both aspects of the disorder, which in turn produce remission from tobacco addiction.

Treatment approaches that minimize the symptoms associated with abstinence, including craving, have been effective at helping people to achieve and sustain abstinence from tobacco. Recent studies of nicotine-replacement therapy (involving nicotine polacrilex and transdermally-delivered nicotine) have confirmed the ability of these medications to attenuate the severity of withdrawal symptoms in abstinent cigarette smokers (Hughes et al., 1991; Transdermal Nicotine Study Group, 1991; Tonnesen et al., 1992).

Such approaches are limited by the same kinds of factors that limit the efficacy of pharmacologic adjuncts for treating other kinds of drug dependence and related disorders. One implication of these observations is that evaluation of the utility of specific medications in the alleviation of certain signs and symptoms should not be confused with the evaluation of programs aimed at reducing the prevalence of tobacco use and its associated morbidity and mortality. For example, a medication that provides relief of acute nicotine withdrawal symptoms or selectively prevents cognitive deficits could be useful in a program to help people quit smoking. However, motivating patients to attempt to quit, to take their medications, and providing them with strategies for preventing relapse (including possible long-term maintenance on medications) is the responsibility of the health care professional and the patient. Long-term outcomes, in turn, will be a reflection of the overall strength of the entire treatment program, and not the efficacy of a particular pharmacologic therapeutic adjunct alone.

The diversity of factors that appear relevant to the control and treatment of tobacco use across individuals implies the need for a diversity of treatment approaches. Development of either new medications or more effective ways of using existing medications probably will be required to adequately address diverse patient needs in this important area of medicine and public health.

Nicotine Substitution Therapy

The prominent role of nicotine itself in the mediation of tobacco dependence suggests that replacement therapies might be the most useful form of pharmacotherapy. Nicotine polacrilex was the first approved formulation in the United States for clinical use, and it has a clearly demonstrable efficacy in both laboratory and clinical settings. However, its efficacy appears to be related to the rate and efficiency with which nicotine is extracted and absorbed; patients need very specific instructions on the use of this drug, and clinical follow-up is important. Alternate replacement formulations are needed for those who cannot use the gum for dental and other reasons. Recently, nicotine transdermal patches have largely supplanted nicotine polacrilex as the initial choice for nicotine replacement therapy. Other nicotine replacement approaches under active development include a nasal spray or droplet form, and a nicotine vapor inhaler.

Goals of therapy: While complete abstinence from cigarettes or other forms of tobacco use has been the ideal treatment goal, other goals can be achieved. Nicotine replacement therapy can be used for indications including: (1) relief of specific withdrawal symptoms associated with long-term tobacco abstinence, (2) decreased tobacco use, (3) prevent the relapse to tobacco use behavior, and (4) reverse the toxic effects of cigarette or other tobacco use (Woody et al., under review). Accordingly, nicotine replacement can target specific tobacco withdrawal symptoms (including craving for nicotine, increased appetite/weight gain, suppression of anxiety or restlessness that may persist indefinitely), prevent relapse to tobacco use in situations with high relapse potential (e.g., stressful situations, socializing with other smokers), or halt the progression of tobacco-related disease (including chronic obstructive pulmonary disease, asbestosis, advanced cardiovascular disease) by eliminating the toxic by-products of tobacco use. Also, if treatment produces incomplete abstinence from tobacco use, this should not be viewed as a treatment failure but rather as a partial treatment success. Using a harm-reduction analysis, decreasing total daily tobacco exposure and its accompanying toxic effects by some clinically practical proportion should decrease the risk of suffering many of the adverse effects of long-term tobacco use because these effects are dose and duration-dependent.

Patient selection: The people who benefit the most from adjunctive nicotine replacement appear to be those who experience more severe withdrawal symptoms when nicotine intake is abruptly stopped. In general, patients who have high Fagerstrom Tolerance Questionnaire scores or higher scores on the Fagerstrom Test for Nicotine Dependence (a refinement of the earlier questionnaire) and patients who smoke greater numbers of cigarettes receive increased benefits from adjunctive nicotine gum, while patients who have low scores and patients who smoke fewer cigarettes each day do not. Consequently, highly nicotine-dependent tobacco users should receive higher initial doses of nicotine than do the less dependent users.

Dosing and administration: Nicotine polacrilex gum is available in two doses: 2 and 4 mg. These formulations deliver roughly half of the nicotine contained within the pressure-sensitive resin of a single dose. The resin matrix minimizes the risk of accidental poisoning, since nicotine is released slowly and some chewing is necessary for activation. Patients often find the taste of the gum to be mildly unpleasant. This is deliberate to further reduce the risk of accidental poisoning of a child. Practice and patience are required to obtain an adequate dose of nicotine. The drug is delivered across the buccal mucosa over 30 minutes.

The venous nicotine level rises much more gradually after a dose of nicotine gum than following a cigarette. Past work has shown that the 4 mg. dose of gum is more efficacious than the 2 mg. dose in alleviating symptoms of nicotine withdrawal and helping to maintain abstinence from tobacco use, especially in the severely nicotine dependent patient. However, a clinical determination of the level of nicotine dependence must be made and a decision regarding the dose reached. The more dependent patients should be given a higher dose of medication. Patients should be advised that use of roughly one piece of gum per hour during the day is appropriate, and that the dose of

Continued on next page
The consumption of foods or beverages that contain sugar (Henningfield et al., 1990) can be varied by the physician. Substantially higher doses may be necessary in some situations. Lower doses usually are not particularly helpful.

The patient should be instructed that nicotine gum is an adjunct to a treatment program for nicotine dependence. It will prevent or ameliorate nicotine withdrawal symptoms, but it will not prevent thinking about smoking or experiencing urges to smoke. Because the blood nicotine level does not rise as rapidly with nicotine gum as it does with a cigarette, it is best to take nicotine gum on a schedule, every hour or two for instance, ahead of symptoms (Fortman et al., 1988). Additional doses can be used in an ad libitum manner in addition to the scheduled dose to relieve discomfort. For the most part, the gum should stay in the cheek after an initial few chews render it malleable. In about 30 minutes, all of the nicotine is extracted from the gum. It should be worked around with the tongue and teeth for a few seconds every few minutes, but it should not be chewed constantly. If it is chewed like chewing gum, most of the nicotine will be swallowed instead of absorbed across the buccal mucosa. This may result in an upset stomach, nausea, gas, jaw ache, or throat irritation, along with reduced amounts of nicotine reaching the brain because of first-pass metabolism.

Nicotine absorption in the mouth from nicotine polacrilex use requires a mildly alkaline environment (pH about 8.0). Therefore, consumption of foods or beverages that lower the pH will reduce or block nicotine absorption. This includes most beverages (such as coffee, tea, carbonated beverages, and fruit juices), as well as chewing gums containing sugar (Henningfield et al., 1990). A period of 10 to 15 minutes should elapse after eating or drinking before the next dose of nicotine gum.

Contraindications: Nicotine replacement, whether delivered as gum, patch, or in some other form, is contraindicated in people who are not actively addicted to nicotine and in people who intermix the use of tobacco products with nicotine replacement (e.g., those who use nicotine gum or a patch to temporarily ameliorate nicotine withdrawal when in a place where smoking is not permitted). Also, nicotine replacement should not be used without concomitant behavioral treatment strategies. Nicotine replacement also is contraindicated in individuals with known hypersensitivity to nicotine. Nicotine polacrilex may be difficult or impossible for some patients to use because of dental appliances or concomitant dental or other oral pathology. Transdermal nicotine replacement therapy may be contraindicated in certain patients with severe dermatological disease.

Nicotine replacement is contraindicated in situations where vascular compromise or arrhythmia may be induced or worsened by nicotine. These situations include the immediate post-myocardial infarction period, life-threatening arrhythmias, and worsening angina pectoris. The use of nicotine replacement also is discouraged in pregnant patients, and the labeling for nicotine gum cautions against prescribing it in patients who might become pregnant. At the same time, nicotine replacement may be an essential part of helping a patient who has vascular disease or who is pregnant to stop smoking or be comfortable in not smoking at a critical time. The toxicity of cigarettes is greater in nearly every respect than that of either nicotine gum or patch, including the rate of nicotine delivery to the tissues and the levels of peak and steady state blood nicotine concentrations (Benowitz, 1991). Consequently, the risks of further nicotine use must be weighed against the benefits of cigarette smoking cessation and the elimination of the toxicity associated with further tobacco use.

Therapy duration: Optimally, nicotine gum should be used for several months. Regular use in the first month is the most important. Most patients can comfortably reduce their use gradually after this interval. Longer periods, up to a year or so, may benefit some patients. To wean off the gum, some patients will benefit from a weaning plan. Schneider (1988) suggests several useful weaning strategies (i.e., cutting daily dose by one piece per week, cutting gum pieces in half, breaking up gum rituals). Another approach is to slowly increase the drug-free interval, which begins with each night’s sleep, extending this into the morning hours, then the afternoon hours; and finally into the evening over a period of weeks (Cooper and Clayton, 1988).

Some patients cannot be weaned from nicotine gum without a prompt relapse to tobacco use. Management options in this instance include attempting more gradual weaning efforts and/or gradually substituting chewing gum for the polacrilex (Waranch, Henningfield and Edmunds, 1988) or simply continuing to maintain the patient on nicotine gum indefinitely after appropriate counseling.

With the transdermal nicotine delivery systems, each level of treatment (employing the various doses) should last from one to two months. At that time, intermittent daily use of the patch may be attempted, or the patient could be maintained on nicotine polacrilex ad libitum for some period of time to help with certain withdrawal symptoms and/or to prevent relapse to tobacco use in high-risk situations.

Antagonist Therapies
A pharmacologic alternative to agonist replacement therapy is the pharmacologic blockade of receptors that mediate the reinforcing as well as toxic effects of an abused

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NIH Convenes Conference on Liver Transplantation for Alcoholic Liver Disease

A two-day international workshop on Liver Transplantation for Alcoholic Liver Disease is to be held December 6-7, 1996, at the Bethesda Marriott Hotel and the Natcher Conference Center on the NIH Campus in Bethesda, Maryland. Co-sponsored by the National Institute on Alcohol Abuse and Alcoholism and the Division of Digestive Diseases of the National Institute of Diabetes and Digestive and Kidney Diseases, the conference aims to review the current status and rates of success of liver transplantation for alcoholic liver disease, to make recommendations for selection and management of alcoholic patients undergoing liver transplantation, and to suggest directions for future clinical and basic research. Registration is $25, and a limited number of scholarships are available to support the travel of young investigators. For more information, contact Mr. Jere Suter, Conference Manager, at ComputerCraft Corporation, 6707 Democracy Blvd., Suite 101, Bethesda, MD 20817; phone 301/493-9674 or fax 301/530-0634.
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...drug (Jaffe, 1985). An example of one such currently available therapy is the use of the opioid antagonists, naltrexone and naloxone. In the case of opioids, such as morphine and heroin, the short-acting opioid antagonist naloxone is used to reverse the effects of an opioid overdose. The longer-acting opioid antagonist naltrexone is given on a daily basis to opioid abusers to prevent the reinforcing and toxic effects of opioid abuse. While these therapies have known efficacy, few opiate-dependent patients remain on a therapeutic regimen of naltrexone for various reasons. However, for the highly motivated patient who is medication compliant, antagonist therapy is invaluable in preventing "experimentation" or "slips" from developing into full-blown relapses. Unfortunately, in the case of nicotine antagonist therapy, the nicotine blockers that have been studied either have little effect on smoking (e.g., pentolinium) or have a range of undesirable actions in their own right (e.g., mecamylamine produces sedation and orthostatic hypertension). Nonetheless, preliminary experimental evidence suggest that this approach warrants further investigation.

Blockade approaches (e.g., naltrexone) have not been acceptable for more than a few highly compliant patients. However, such approaches seem important to pursue, since the potential absolute numbers of persons who could benefit from such approaches is considerable (e.g., if five percent of the estimated 50 million people who smoke could be helped, they would total 2.5 million persons). Mecamylamine is available at present, but its use probably will be constrained by its unpleasant ganglionic blocking actions. A more selective, centrally acting blocker, which could be analogous to naltrexone for opiate dependence, would be highly desirable.

Nonspecific Pharmacotherapies
Another potentially useful but not widely used approach is nonspecific pharmacotherapy. This is the use of agents that do not act on nicotine or nicotinic receptors, but that produce symptomatic relief from the various sequela of tobacco abstinence, which range from the specific nicotine abstinence effects described in DSM-IV to the occasional severe affective symptoms that may be part of the short-term withdrawal syndrome from nicotine, the more protracted phase of nicotine withdrawal, or emergent symptoms which had been suppressed by the chronic use of tobacco. Fortunately, therapeutic strategies are available for many such symptoms (e.g. anxiety, depression, and weight control), which can occur independently of nicotine dependence and withdrawal. Therefore, it is plausible that medications that do not provide significant benefit for unselected groups of smokers may still be appropriately used on an individual case basis. For instance, the use of benzodiazepines and anorectants should not be ruled out simply because such drugs may increase smoking in persons not trying to quit. There seems to be modest benefit from the adjunctive use of clonidine, although it is unclear whether there are particular subpopulations for which this drug might be especially helpful. Similarly, even though there is as yet little evidence for the use of antidepressants to treat tobacco dependence, it is plausible that they could facilitate abstinence in selected individuals. Such pharmacologic approaches probably would benefit from concurrent behavioral treatment.

Deterrent approaches, in principle, could be of enormous potential utility. However, a satisfactory nicotine deterrent has yet to be developed and marketed. The challenge is to produce a product that reliably leads to consequences that are both sufficiently severe and immediate to discourage smoking, and without side effects that would act to inhibit its use (e.g. the staining of gums caused by silver salts).

Conclusions
There is a strong rational basis, and even some direct evidence, that pharmacologic intervention for the treatment of cigarette smoking could be of significant therapeutic value. The efficacy of pharmacologic intervention may be limited by the extent to which the substance seeking behavior, and the derived rewards, have become functionally autonomous from the drug itself. However, this problem is not unique to tobacco. It is well known that effective programs for assisting opiate users in achieving long-term abstinence, for instance, involve considerably more means of intervention than simply blocking physiologic withdrawal symptoms. An entire "life style" may require change (Bigelow, Stitzer and Liebson, 1985; Grabowski and Hall, 1984). By the time the dependent cigarette smoker attempts to quit, there usually have been hundreds of thousands of pairings of various effects of nicotine with the stimuli provided by the use of the tobacco product. These stimuli certainly are not replaced by any pharmacologic agent, and much time may be required until their absence no longer contributes to the discomfort of withdrawal and the occurrence of relapse. Perhaps the most that pharmacologic intervention can provide is a means to alleviate the physiologically-mediated components of withdrawal and their contribution to relapse. The best will be up to intervention program and the contingencies set by the patients themselves.

References


Alcohol and Stress

The term "stress" often is used to describe the subjective feeling of pressure or tension. However, when scientists refer to stress, they mean the many objective physiological processes that are initiated in response to a stressor. As this Alcohol Alert explains, the stress response is a complex process; the association between drinking and stress is more complicated still. Because both drinking behavior and an individual's response to stress are determined by multiple genetic and environmental factors (1-3), studying the link between alcohol consumption and stress may further our understanding of drinking behavior.

The Stress Response

The maintenance of the body's relatively steady internal state, or homeostasis, is essential for survival. The body's delicate balance of biochemical and physiological function is constantly challenged by a wide variety of stressors, including illness, injury, and exposure to extreme temperatures; by psychological factors, such as depression and fear; and by sexual activity and some forms of novelty-seeking. In response to stress, or even perceived stress, the body mobilizes an extensive array of physiological and behavioral changes in a process of continual adaptation, with the goal of maintaining homeostasis and coping with the stress (4).

The stress response is a highly complex, integrated network involving the central nervous system, the adrenal system, and the cardiovascular system. When homeostasis is threatened, the hypothalamus gland, at the base of the brain, initiates the stress response by secreting corticotropin releasing factor (CRF). CRF coordinates the stress response by triggering an integrated series of physiological and behavioral reactions. CRF is transported in blood within the brain and in seconds triggers the pituitary gland to release adrenocorticotropin hormone (ACTH), also referred to as corticotropin. ACTH then triggers secretion of glucocorticoid hormones (i.e., "steroids") by the adrenal glands, located at the top of the kidneys. Glucocorticoid hormones play a key role in the stress response and its termination (4).

Activation of the stress response affects smooth muscle, fat, the gastrointestinal tract, the kidneys, and many other organs and the body functions that they control (4). The stress response affects the body's regulation of temperature; appetite and satiety; arousal, vigilance, and attention; mood; and more (4). Physical adaptation to stress allows the body to redirect oxygen and nutrients to the stressed body site, where they are needed most (4).

Both the perception of what is stressful and the physiological response to stress vary considerably among individuals. These differences are based on genetic factors and environmental influences that can be traced back to infancy (5).

Stress is usually thought of as harmful; but when the stress response is acute and transient, homeostasis is maintained and no adverse effects result. Under chronic stress, however, when the body either fails to compensate or when it overcompensates, damage can occur (4). Such damage may include suppression of growth, immune system dysfunction, and cell damage resulting in impaired learning and memory (4,6).
**Does Stress Influence Drinking?**

Human research to clarify the connection between alcohol and stress usually has been conducted using either population surveys based on subject self-reports or experimental studies. In many but not all of these studies, individuals report that they drink in response to stress and do so for a variety of reasons. Studies indicate that people drink as a means of coping with economic stress, job stress, and marital problems, often in the absence of social support, and that the more severe and chronic the stressor, the greater the alcohol consumption (7). However, whether an individual will drink in response to stress appears to depend on many factors, including possible genetic determinants of drinking in response to stress, an individual’s usual drinking behavior, one’s expectations regarding the effect of alcohol on stress, the intensity and type of stressor, the individual’s sense of control over the stressor, the range of one’s responses to cope with the perceived stress, and the availability of social support to buffer the effects of stress (1,2,7,8). Some researchers have found that high levels of stress may influence drinking when alternative resources are lacking, when alcohol is accessible, and when the individual believes that alcohol will help to reduce the stress (1,8).

Numerous studies have found that stress increases alcohol consumption in animals (9) and that individual animals may differ in the amount of alcohol they consume in response to stress (10). Such differences may be related in part to an animal’s experiencing chronic stress early in life: Prolonged stress in infancy may permanently alter the hormonal stress response and subsequent reactions to new stressors, including alcohol consumption (10,11). For example, monkeys who were reared by peers, a circumstance regarded as a stressor compared to mother-rearing, consumed twice as much alcohol as monkeys who were mother-reared (10). According to Viau and colleagues (11), adult rats handled for the first 3 weeks of life demonstrate markedly reduced hormonal responses to a variety of stressors compared with rats not handled during this time (11). In humans, Cloninger reported an association between certain types of alcoholism and adverse early childhood experiences (12).

Animal studies reporting a positive correlation between stress and alcohol consumption suggest that drinking may take place in response to chronic stress perceived as unavoidable (2,13). For instance, rats chronically exposed to unavoidable shock learn to be helpless or passive when faced with any new stressor—including shock that is avoidable—and to demonstrate increased alcohol preference compared with rats that received only avoidable shock (2). The rats exposed to unavoidable shock exhibit the hormonally changes indicative of the stress response, including increased levels of corticosteroid hormones (2).

Whether humans drink in response to uncontrollable stress is less clear, according to Pohorecky (7). In a review investigating the connection between alcohol consumption and stress, Pohorecky notes several studies in which researchers sampled individuals from areas affected by natural disaster. One study found that alcohol consumption increased by 30 percent in the 2 years following a flood at Buffalo Creek, West Virginia. Similarly, there was evidence of increased drinking in the towns surrounding Mount St. Helens following eruption of the volcano (7). Following the nuclear plant accident at Three Mile Island, however, alcohol consumption was infrequently used by those sampled as a means of coping with the resulting stress (14).

In both humans and animals, drinking appears to follow stress (2,3,7,13). Some human research, however, shows that drinking may take place in anticipation of or during times of stress (15).

**Does Drinking Reduce or Induce Stress?**

Some studies have reported that acute exposure to low doses of alcohol may reduce the response to a stressor in animals and humans. For example, low doses of alcohol reduced the stress response in rats subjected to strenuous activity in a running wheel (3). In humans, a low dose of alcohol improved performance of a complex mental problem-
solving task under stressful conditions (3). However, in some individuals, at certain doses, alcohol may induce rather than reduce the body's stress response (16).

Much research demonstrates that alcohol actually induces the stress response by stimulating hormone release by the hypothalamus, pituitary, and adrenal glands (4,6,17,18). This finding has been demonstrated in animal studies. In one study with rats, the administration of alcohol initiated the physiological stress response, measured by increased levels of corticosterone (19). In addition to stimulating the hormonal stress response, chronic exposure to alcohol also results in an increase in adrenaline (20).

**Stress, Alcoholism, and Relapse**

Stress may be linked to social drinking, and the physiological response to stress is different in actively drinking alcoholics compared with nonalcoholics (17). Researchers have found that animals preferring alcohol over water have a different physiological response to stress than animals that do not prefer alcohol (21). Nonetheless, a clear association between stress, drinking behavior, and the development of alcoholism in humans has yet to be established.

There may, however, in the already established alcoholic, be a clearer connection between stress and relapse: Among abstinent alcoholics, personally threatening, severe, and chronic life stressors may lead to alcohol relapse (15,22). Brown and colleagues (15) studied a group of men who completed inpatient alcoholism treatment and later experienced severe and prolonged psychosocial stress prior to and independent of any alcohol use. The researchers found that subjects who relapsed experienced twice as much severe and prolonged stress before their return to drinking as those who remained abstinent. In this study, severe psychosocial stress was related to relapse in alcoholic males who expected alcohol to reduce their stress. Those most vulnerable to stress-related relapse scored low on measures of coping skills, self-efficacy, and social support. Stress-related relapse was greatest among those who had less confidence in their ability to resist drinking and among those who relied on drinkers for social support. Although many factors can influence a return to drinking, Brown and colleagues note that stress may exert its greatest influence on the initial consumption of alcohol after a period of abstinence (15).

**Drinking and Stress—A Commentary by NIAAA Director Enoch Gordis, M.D.**

Stress is commonly believed to be a factor in the development of alcoholism (alcohol dependence). However, current science is more informative about the relationship between drinking and stress than about the relationship between stress and alcohol dependence.

Drinking alcohol produces physiological stress, that is, some of the body's responses to alcohol are similar to its responses to other stressors. Yet, individuals also drink to relieve stress. Why people should engage in an activity that produces effects similar to those they are trying to relieve is a paradox that we do not yet understand. One hypothesis is that stress responses are not exclusively unpleasant; the arousal associated with stress itself may be rewarding. This might explain, for example, compulsive gambling or repeated participation in "thrill-seeking" activities. Current studies may illuminate genetic variations in the physiological response to stress that are important in drinking or other activities with the potential to become addictive.

Training clinical staff to accurately appraise patients' drink-provoking stressors may help staff to identify individuals at risk for relapse. One route to relapse prevention is the teaching of coping skills where patients learn how to deal with these stressors without drinking. How this treatment approach compares with others remains of special interest.
References

Advertising Shapes Teens' Cigarette Choices

For years, the tobacco industry has insisted that its advertising is aimed at inducing adults to change brands and that it has little effect on young people. But after a 1995 study reported that a high percentage of children aged three to six associated the “Joe Camel” ad campaign with cigarettes, a group of researchers from the U.S. and Canada set out to determine how sensitive 12- to 18-year-olds are to cigarette advertising. They report in the April Journal of Marketing that cigarette advertising not only influences adolescents’ brand choices, but that when advertising intensity doubles, it has three times the effect on teens’ choices as on adults’.

“If I am a cigarette manufacturer, it means that if I double my advertising, adolescents will flock to me three times faster than adults; adults are brand loyal,” said Richard W. Pollay, lead author of the study. “We call this the battle of the brands,” he added. “It is teens who hear the battle cry, and teens who are the victims of it.”

Addiction Medicine Reshaped by Managed Care

The specialty of addiction medicine is being reshaped by managed health care, advances in the neuroscience of addiction, and availability of new treatment pharmacotherapies, say Drs. Donald R. Wesson and Walter Ling in their overview in the annual review issue of the Journal of the American Medical Association (1996;23:1792-1793). The practices of managed health care in reducing treatment access and length of inpatient treatment have not been studied adequately, they add, but there is reason for concern.

To justify denying inpatient treatment beyond detoxification, managed health care representatives often cite studies showing that treatment outcomes for patients treated in hospitals are about the same as outcomes for patients treated as outpatients. This overgeneralizes available data, the authors warn. They conclude that, as in other areas of medicine, the challenge for addiction medicine physicians is to continue providing patients with the care they need, despite daunting regulatory and economic barriers.

Molecular Mechanisms of Cocaine Addiction

A recent study published in the journal Nature (Giro et al., 1996;379:606-612) affirms the central importance of the dopamine-reuptake transporter in the behavioral and biochemical action of cocaine and defines it as a site on which efforts to develop an anti-cocaine medication should be focused. The authors produced a strain of mice in which the gene encoding the dopamine transporter was disabled. These mice did not respond to cocaine either biochemically or behaviorally, thus demonstrating that the transporter is necessary for cocaine to produce its psychostimulant effects. (Mice with the same deficiency also are being used to help answer questions about Parkinson’s disease and certain psychiatric disorders that, like the effects of cocaine, are linked to a malfunction in the regulation of neurotransmission by dopamine.)

Marijuana Impairs Workplace Performance

Marijuana use is linked to a pattern of behaviors that leads to poor job performance, according to a study presented at NIDA’s first National Conference on Marijuana Use. Dr. Wayne Lehman of Texas Christian University looked at how marijuana affects job performance. In a series of surveys of 4,600 municipal employees in four cities in the Southwest, Lehman found that employees who reported marijuana use were different from nonusers: they were more likely to have arrest histories, low self-esteem, high rates of depression, and friends who are deviant. This behavioral pattern in the personal backgrounds of marijuana-smoking employees was associated with negative attitudes toward work and job performance, Dr. Lehman said. The marijuana-using workers reported more absenteeism, tardiness, accidents, workers’ compensation claims, and job turnover. They also were more likely to report to work with a hangover, miss work because of a hangover, and be drunk or use drugs at work.

Preventing Adolescent Alcohol Use

A combination of classroom and community interventions can successfully reduce alcohol use by young adolescents, according to initial findings from a nine-year study funded by the National Institute on Alcohol Abuse and Alcoholism (NIAAA). Reported in the July 1996 issue of the American Journal of Public Health (1996;86:956-965), the study found that the onset of alcohol use by students in the intervention communities was reduced by 28% compared with control communities.

These initial findings indicate that “multilevel, targeted prevention programs for young adolescents are effective,” concluded principal investigator Cheryl L. Perry, Ph.D., and her colleagues at the University of Minnesota. Copies of the program curricula may be obtained by contacting Dr. Perry by phone at 612/624-4188 or by fax at 612/624-0315.

Physicians’ Role in Helping Patients Secure Smoke-Free Workplaces

Physicians have an essential role in ensuring that the goals of the Americans with Disabilities Act are met in terms of their application to smoking policy, say the authors of a report in the Journal of the American Medical Association (1996;276:909-913).

Attorneys Wendy Parmet, Richard Daynard and Mark Gottlieb maintain that physicians play a key role in educating patients, employers and the public as to the medical consequences of exposure to environmental tobacco smoke (ETS), particularly to children and patients who are disabled. Moreover, they can clarify to patients that avoiding exposure to ETS is essential medical advice that they have a legal right to follow. Finally, physicians can play an important role as community leaders by helping their friends, neighbors, colleagues and other citizens understand the dangers posed by ETS and how it can harm some of the most vulnerable patients. Only then, the authors conclude, will the public understand that the presence of ETS is not a mere annoyance, but a health hazard and often a violation of a basic civil right.

FROM THE LITERATURE

Come Practice Psychiatry in the Beautiful Southwest

Remuda Treatment Center is a progressive facility located on a guest ranch setting 50 miles northwest of Phoenix. Remuda individualizes FX for eating disordered females meeting medical, nutritional & psychological needs. blended with a Biblical perspective. We are seeking a BC/BE psychiatrist interested in eating disorder treatment. We offer a charming resort town atmosphere, excellent salary and very predictable schedule. E.O.E.

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and cultural events will be the last to take effect—in two years—so that alternative sponsors can be arranged for the affected events.

Advertisers have said they will join tobacco producers in fighting the new rules as an unconstitutional restriction on free speech. The Supreme Court in May bolstered First Amendment protections of truthful advertising that involves drinking, smoking or other conduct the government deems harmful. The court unanimously struck down a Rhode Island ban on the advertising of liquor prices. Although the justices splintered in their legal reasoning, they agreed that courts should be wary of restrictions on advertising that is neither false nor misleading.

However, unlike the Rhode Island liquor case, the President's tobacco plan focuses on advertising aimed at minors. The government's interest in protecting children's health likely would be an important factor in court review of the new regulations. "We think the rule is very defensible in court," the FDA's Kessler said.

But industry groups expressed outrage. "We're absolutely devastated," said Lisa Eddington, managing director of the National Tobacco Council, which represents tobacco growers as well as other parts of the industry. "It's both unnecessary and unfair." Eddington said that implementing the rules could cost "some­where in the neighborhood of 10,000 jobs, and 60 percent of those would be in the tobacco grower sector."

While acknowledging the potential for job loss (which the administration estimates at 2,500 over seven years), the President said the rules are "the right thing to do, scientifically, legally and morally." Every day, he said, about 3,000 young people start smoking and nearly 1,000 of them will die prematurely from cancer, emphysema, heart disease and other ailments caused by tobacco products. "This epidemic is no accident," Clinton added. "Children are bombarded daily by massive marketing campaigns that play on their vulnerabilities, their insecurities, their longings to be something in the world. Joe Camel promises that smoking will make you cool. Virginia Slims models whisper that smoking will help you stay thin."

NEW TOBACCO REGULATIONS ANNOUNCED BY PRESIDENT CLINTON

Billboards and Signs
Billboards and signs are limited to black-and-white text only, except in adult-only facilities. Tobacco billboards are banned within 1,000 feet of schools and playgrounds.

Print Ads
Only black-and-white text-only ads are allowed in publications whose youth readership is more than 2 million, or 15 percent of total readership.

Vending Machines
Cigarette vending machines are limited to facilities where children are prohibited.

Giveaways
No product giveaways are allowed with brand names or brand logos.

Sponsorship
Entertainment or sporting events can be sponsored only in the corporation's name, not a tobacco brand name.

Photo IDs
Buyers under age 27 must produce photo identification.

Education
An industry-run educational campaign about the health risks of tobacco use (to be monitored by the FDA) is required.

Samples
Distribution of free samples, as well as sale of single cigarettes or packs of less than 20 cigarettes, is prohibited.


ASAM DELIVERED STRONG SUPPORT FOR NEW TOBACCO RULES

John Slade, M.D., prepared ASAM's comments in support of the FDA effort to regulate tobacco products as nicotine delivery devices. For example, on January 2, 1996, ASAM delivered four banker's boxes of materials to the FDA's offices in Rockville, MD. The boxes contained ASAM's comments on the agency proposal, along with 19 binders of supporting materials, including tobacco product promotional items such as a Benson & Hedges cap, some Camel lighters and a Newport T-shirt.

In an accompanying letter, ASAM President David E. Smith, M.D., told FDA Commissioner Kessler that the American Society of Addiction Medicine (ASAM) fully supports the FDA in its determination that the nicotine in cigarettes and smokeless tobacco products that contain nicotine are drugs and nicotine delivery devices. The regulatory framework described in the Federal Register of August 11, 1995, for these nicotine delivery devices represents a major advance for public health in the United States. The Society supports the enactment of the Agency's proposal in substantially the same form as it has been proposed, but as the enclosed comment indicates, there are some parts of the proposal that ASAM believes should be strengthened.

Dr. Smith noted that "nicotine addiction is the most serious addiction problem in the nation because of the vast number of people affected and the enormous suffering it causes. As you have so rightly said, it is a pediatric disease."

The Society's comments on the Agency's proposal were in three parts. Part A discusses the Agency's assertion of jurisdiction over cigarettes and smokeless tobacco products, while Part B considers the proposed regulation and its supporting materials as published in the Federal Register of August 11, 1995. Both of these comments were accompanied by extensive appendices. Part C was responsive to the Agency's request for comment on the focus group testing of the brief statements warning of health hazards it described in the Federal Register of December 1, 1995.

Dr. Smith's letter concluded that "ASAM is grateful for your courage, determination and deep understanding of the issues that have created and perpetuated the tobacco epidemic. The Society looks forward to continuing its support of your efforts to reduce the terrible toll of addiction, disease and death that tobacco products bring to all too many people."
ASAM POLICY STATEMENTS ON NICOTINE DEPENDENCE

As early as 1988—the year Surgeon General C. Everett Koop, M.D., released the first federal report acknowledging that tobacco is addictive—the ASAM Board of Directors prepared an official policy statement on the subject. Others have followed, and their chronology traces the progress of scientific understanding of the nature and treatment of nicotine dependence.

1988: Nicotine Dependence and Tobacco. After asserting that “Regular use of tobacco products leads to addiction in a high proportion of users,” the report concludes that “Nicotine dependence is a primary medical problem deserving of thoughtful, ongoing attention from every responsible clinician. Diseases caused by tobacco use should be regarded as complications of nicotine dependence.” The policy statement then calls for a number of national initiatives, including steps to reduce the availability of tobacco products to the young, assigning responsibility for regulating all tobacco-containing products to the Food and Drug Administration, strengthening the warning system on cigarettes and smokeless tobacco, eliminating all advertising and promotional activities for nicotine-containing tobacco products, implementing smoke-free workplaces and public spaces, initiating legal action against the tobacco industry (including law suits by the states), and supporting research into the nature of nicotine addiction and its treatment and prevention. (Revised in 1996.)

1989: Documentation of Nicotine Dependence on Death Certificates and Hospital Discharge Sheets. Observing that “nicotine dependence is the most common drug dependence in the country,” which “contributed to 395,000 deaths in 1985, and to numerous hospitalizations,” the report affirms that “physicians have a major role to play in recognizing and managing nicotine dependence in their patients.” To that end, the report calls for clear documentation of tobacco use as a contributing cause of death in death certificates, and of tobacco use in relation to hospitalizations, to increase awareness of the health effects of tobacco and to provide epidemiologic data needed for future research.

1990: Reimbursement for the Treatment of Nicotine Dependence. The report affirms that “nicotine dependence is the most common form of chemical dependence in the United States” and urges the adoption of third-party reimbursement for the treatment of nicotine dependence, so as to make treatment available to persons of limited means and to encourage entry into treatment at earlier stages. The report also encourages employers to sponsor on-site programs to help employees quit smoking.

1992: Clinical Applications of the Nicotine Patch. After endorsing the use of the transdermal nicotine patch as “a useful adjunct in the treatment of nicotine addiction,” the report cautions that the patch alone is not treatment for the addiction and urges that the nicotine patch be used only as part of a planned strategy to stop tobacco use.

HISTORY OF TOBACCO REGULATION IN THE U.S.

1950: Three published epidemiological studies indicate a correlation between cigarette smoking and lung cancer.

1957: Surgeon General Leroy E. Burney issues a report stating that “excessive” smoking appears to be “one of the factors in lung cancer.”


1966: The federal Cigarette Labeling and Advertising Act takes effect, requiring warning labels on cigarette packaging.


1970: Congress strengthens cigarette warning labels.

1971: TV and radio ads for cigarettes are banned as the Cigarette Smoking Act of 1969 takes effect.

1973: The Civil Aeronautics Board requires no-smoking sections on commercial flights. Arizona becomes the first state in modern times to restrict smoking in public places.

1975: Cigarettes are discontinued in military rations.

1983: San Francisco becomes the first city to ban smoking in private workplaces.


1988: Surgeon General Koop issues a report declaring that cigarette smoking is “addictive.”

ASAM adopts a policy statement calling for specific steps to reduce the promotion and availability of tobacco products to young people.

1990: A federal ban on smoking on intercity buses and domestic airlines flights of six hours or less takes effect. The Secretary of HHS denounces advertising for Uptown cigarettes, which is targeted to African-American audiences; the manufacturer cancels marketing plans.

1993: The federal Environmental Protection Agency issues a report identifying second-hand smoke as a health risk. President Clinton ban smoking in the White House.

1994: FDA Commissioner David Kessler announces that the agency is studying regulating tobacco products. The federal Occupational Health and Safety Administration proposes regulations banning workplace smoking or requiring separate, specially ventilated smoking rooms.

1995: The FDA announces proposals to restrict tobacco marketing and sales. In its Federal Register filing, the FDA states that “based on the evidence now before the agency, cigarettes and smokeless tobacco products are drug delivery systems whose purpose is to deliver nicotine.”

1996: ASAM delivers four banker’s boxes, containing more than 40,000 pages of scientific evidence (compiled by Dr. John Slade) in support of the FDA’s proposed rules.

ASAM President David E. Smith writes to President Clinton, urging that the administration move ahead with approval of the FDA’s proposed rules.

President Clinton announces his approval of the FDA’s proposed rules, allowing the agency to enforce them as federal law.
ASAM CALLS ON FDA TO REGULATE “ECLIPSE”

ASAM has requested the federal Food and Drug Administration to regulate Eclipse, a new nicotine delivery device being test-marketed by the R.J. Reynolds Tobacco Co., of Chattanooga, Tennessee.

In a letter to FDA Commissioner David Kessler, Dr. John Slade, Chair of ASAM’s Committee on Nicotine Dependence, urged that Eclipse be regulated to assure that it will result in more good than harm to the public health. Dr. Slade also cautioned the FDA not to deal with Eclipse apart from other nicotine products; rather, he pointed out that Eclipse raises issues that the FDA has not addressed in the new rules under which it is authorized to regulate tobacco products for the good of children. His letter cites the following reasons for regulation of Eclipse and similar nicotine delivery devices:

- The safety and toxicity of these products should be assessed by an independent body, which can determine if the data are sufficient to warrant offering the device to the public, and can determine the conditions for sale.

- Marketing of a nicotine delivery system could have unintended consequences. For example, while a product less harmful than cigarettes might be advantageous if its use were limited to persons who would not otherwise stop using tobacco, it could be detrimental, since it is not completely safe, if it were used by persons who otherwise would become abstinent or who had not previously used nicotine. A regulatory agency like FDA would be able to set limits and monitor usage in ways that assure that good intentions lead to good results.

- Although initial advertising for these devices may be largely explanatory, marketing campaigns are likely to revert to image-based advertising of the kind now used to sell conventional cigarettes, unless there is regulation.

- A regulatory structure is needed to provide a consistent approach to the marketing of the many different nicotine delivery devices expected on the market from diverse sources in coming years.

- Because nicotine is addictive and Eclipse in particular is designed to deliver nicotine like a conventional cigarette, consumers will not be able to choose easily when to stop. This abridgement of free will means that the government has a special interest in intervening actively to assure the greatest flow of information about these devices and the least amount of disease and death from their use.

The letter was submitted as a comment on citizen petitions regarding Eclipse that have been filed with the FDA by Action on Smoking and Health and the Coalition on Smoking OR Health. (A copy of the letter submitted to the FDA can be downloaded from the ASAM’s site on the World Wide Web at http://members.aol.com/asamoffice.)

ASAM MEMBERS NOMINATED FOR TOP AMA AWARDS

ASAM has nominated Dr. David Kessler of the U.S. Food and Drug Administration and several of its own members for distinguished achievement awards bestowed annually by the American Medical Association.

1996 Nathan Davis Award

ASAM has nominated FDA Commissioner David A. Kessler, M.D., for this award, which is one of the most prestigious extended to elected and career public servants. It is given for outstanding endeavors to advance the public health.

In nominating Dr. Kessler, ASAM said that he has “energetically, courageously and creatively presided over the U.S. Food and Drug Administration” and noted that, as a pediatrician, Dr. Kessler “has taken a strong stand... for eliminating the marketing and sale of tobacco products to young people.”

ASAM’s nomination concludes that “no one characterizes better than Dr. David Kessler the spirit of the Dr. Nathan Davis Awards, which are given to ‘promote the art and science of medicine and the betterment of public health.’”

Scientific Achievement Award

ASAM member Charles S. Lieber, M.D., has been nominated for the Scientific Achievement Award, which is given to a physician or non-physician scientist selected by the AMA Board of Trustees for outstanding scientific achievements.

Dr. Lieber was cited for achievements that include discovery of a new, alcohol-inducible pathway for ethanol metabolism in liver microsomes, involving a unique form of cytochrome P450 (now called 2E1), which explains the interactions of alcohol with other drugs and the vulnerability of the heavy drinker to the hepatotoxicity of commonly used medications, anesthetics, industrial solvents, carcinogens and even vitamins, as well as E-carotene.

Dr. Lieber also uncovered new pathways of hepatic vitamin A metabolism, as well as several metabolic effects of ethanol, such as hyperuricemia, ketosis and increased blood HDL. His work also has elucidated the respective roles of nutritional and toxic factors in the pathogenesis of alcoholic liver disease. Dr. Lieber has authored over 800 scientific publications and nine books, and has held 38 Visiting Professorships worldwide.

Benjamin Rush Award for Citizenship and Community Service

ASAM member John Slade, M.D., has been nominated for this award, which is given for contributions to the community above and beyond the call of duty as a practicing physician.

Dr. Slade’s accomplishments include development of the concept of nicotine dependence as a disease of adolescence—a concept that provided the scientific basis for efforts by the Food and Drug Administration and the President to limit the marketing and sales of tobacco products to young people.

Dr. Slade has been involved in clinical and public health activities around tobacco for more than a dozen years, and recently played a
Continued from previous page

major role in the exposition of tobacco industry documents demonstrating industry knowledge of the addictive properties of nicotine. His publications include two critically acclaimed works, one for the profession (Nicotine Addiction: Principles and Management, with C.T. Orleans) and one for the public (The Cigarette Papers, with S.A. Glantz, et al.). Dr. Slade is medical editor of the Tobacco Products Litigation Reporter and Tobacco Control: An International Journal.

AMA-ERF Award for Health Education

ASAM member David C. Lewis, M.D., has been nominated for the AMA-ERF Award, which was established to encourage and recognize the professional and public health education activities of practicing physicians.

Dr. Lewis was cited for his tireless work over 35 years to make a sustained case for the inclusion of alcohol and other drug problems within the mainstream of medical practice and medical education. Dr. Lewis founded and directs the Brown University Center for Alcohol and Addiction Studies, chairs the HRSA-funded Physician’s Consortium on Substance Abuse Education, and has served as president of the Association for Medical Education and Substance Abuse (AMERSA), the professional society devoted to teaching about substance abuse.

Dr. Lewis also initiated the Project ADEPT curriculum for primary care physician training, and recently chaired a Josiah Macy Conference that brought together leaders of the Boards and Residency Review Committees of psychiatry, obstetrics and medical education. Dr. Lewis founded the Rockridge Center for Addiction and Medical Education. Dr. Lewis was awarded the AMA-ERF Award for his work in alcoholism within Arkansas.

California

CSAM provided five scholarships to physicians-in-training for the 1996 Review Course, to be held in Los Angeles in November. Every year since 1993, CSAM has offered the scholarships to all California residency training programs in medicine, family medicine and psychiatry.

Funds to support the scholarship program come from CSAM’s sister organization, the Medical Education and Research Foundation for the Treatment of Alcoholism and Other Drug Dependencies. In 1992, CSAM members Diane Hambrick, M.D., and Ted Williams, M.D., arranged for a donation from the medical staff of an addiction treatment program in Orange County, which was designated for the purpose of training residents in California. With that donation, the Foundation began the annual scholarship program.

Georgia

Georgia ASAM members can participate in recruiting new ASAM members and win prizes, including one-year free ASAM membership and one free 1997 Med-Sci Conference registration. For more information, contact the chapter office at 404/377-9398.

The Fourth Southern Regional Addiction Conference was held in Savannah, October 17-20. Keynote speakers for the gathering, which focused on Addiction Treatment and Psychiatric Co-Morbidities: Providing Quality Treatment in a Managed Care Environment, were ASAM President-Elect G. Douglas Talbott, M.D. and ASAM Executive Vice President Dr. James F. Callahan. Mr. Gerald Shulman presented on the ASAM PPC-2 and Managed Care, while Steven Jaffe, M.D., led a session on Adolescents and Dual Diagnosis. Charles Whitefield, M.D. presented on Trauma and Recovery.

Missouri

Chapter member Samuel B. Guze, M.D., who is Spencer T. Olin Professor and head of Psychiatry at Washington University School of Medicine, was awarded the Fourth Annual Rhoda and Bernard Sarnat Prize in Mental Health on October 17, 1995. The Sarnat Prize recognizes individuals, groups, or organizations for outstanding achievements in improving mental health. In particular, the award was created to spotlight contributions that improve the understanding of or treatment for mental disorders, innovations in mental health services and public policy changes that improve mental health services. The prize is given by the National Academy of Sciences’ Institute of Medicine. Dr. Guze was selected for the prize because of his pioneering work in a biological approach to the diagnosis and treatment of mental illness.

New Jersey

The New Jersey chapter invites members who are interested in becoming more involved in chapter activities to contact Dr. John Verdon by phone at 908/842-9468 or by fax at 908/842-0666.

South Carolina

SCSAM’s most recent continuing education program, on July 29-30, featured Dr. David Mee-Lee, who addressed a large gathering of physicians, counselors, administrators and state alcohol and drug officials on ASAM’s Patient Placement Criteria, Second Edition (ASAM PPC-2). The response was excellent and SCSAM intends to be active in promoting the ASAM PPC-2 throughout the state as a basis for determining levels of service.

SCSAM President Timothy Fischer, D.O., received the official State Charter during the awards luncheon at the ASAM Med-Sci Conference in April. The chapter currently has 38 members and is actively recruiting more. Plans to develop public service announcements and to work proactively with state officials are ongoing.

Region III Plans Conference on “Addiction Medicine: The 21st Century”

Regional Director Alan Wartenberg, M.D., has invited all Region III members to submit proposals for presentations during the annual conference, November 22-23 at the Hotel Northampton in Northampton, Massachusetts. Proposals should be addressed to Conference Director Panyamurusika Kishore, M.D., in care of Roderick Williams, Ph.D., Conference Coordinator, at 822 Boylston Street, Suite 100, Chestnut Hill, MA 02167.

International

The First Slovenian International Conference on Addiction Medicine was held October 17-19 at Ljubljana, Slovenia. The conference was organized by a committee headed by Zdenka Cebsak-Travnik, M.D., M.Sc. ASAM members interested in the conference may reach Dr. Cebsak-Travnik at the Psychiatric Hospital Ljubljana, Alcoholism Treatment Center, Poljanski nasip 58, 1105 Ljubljana, Slovenia.
Dear Colleague:

As we approach the last months of the year, there is no better time to consider making a charitable gift to the Ruth Fox Memorial Endowment Fund. Your gift will ensure ASAM financial security to carry out its goals well into the future.

Please remember that in order to assure maximum tax savings for your gifts this year, they must be completed by midnight on December 31. All contributions are completely tax-deductible since ASAM is a 501(c)(3) organization.

We are close to reaching our 1996 goal of $2 million. To date, we have received $1,779,756. This total includes contributions, pledges, insurance policies, trust funds and bequests. If you are not a donor, please join your colleagues now, by making a pledge/contribution. All pledges can be paid over five years. If you are already a donor, please consider making an additional contribution, or increasing your current pledge. If you are retired, why not consider a bequest which can be acknowledged now?

All donors will receive an invitation to the Ruth Fox Memorial Endowment Reception scheduled for Friday, April 18, 1997 in San Diego, at which time recognition and medals will be presented to donors who have pledged/contributed $5,000+.

Please help us reach the 1996 goal. If you would like to discuss various ways to support the Endowment Fund, or would like to make a pledge, contribution or bequest, please call Ms. Claire Osman. Her new telephone number is 1/800-257-6776.

Max A. Schneider, M.D.
Chair, Endowment Fund

Jasper G. Chen See, M.D.
Chair Emeritus, Endowment Fund

Claire Osman
Director of Development

NEW IN PRINT

The federal Center for Substance Abuse Treatment offers a number of titles in its Treatment Improvement Protocols (TIPs) series, including: State Methadone Treatment Guidelines (TIP No. 1), Pregnant, Substance-Abusing Women (TIP No. 2), Screening and Assessment of Alcohol and Other Drug-Abusing Adolescents (TIP No. 3), and Guidelines for the Treatment of Alcohol and Other Drug-Abusing Adolescents (TIP No. 4).

Also, Intensive Outpatient Treatment for Alcohol and Other Drug Abuse (TIP No. 8), Simple Screening Instruments for Outreach for Alcohol and Other Drug Abuse and Infectious Diseases (TIP No. 11), Treatment for HIV-Infected Alcohol and Other Drug Abusers (TIP No. 15), Detoxification from Alcohol and Other Drugs (TIP No. 19), Matching Treatment to Patient Needs in Opioid Substitution Therapy (TIP No. 20), and LAAM in the Treatment of Opiate Addiction (TIP No. 22).

Single copies of the TIPs are available at no charge from the National Clearinghouse for Alcohol and Drug Information (NCADI), 1/800-729-6686, or write to CSAT--Publications, Rockwall II Bldg., Suite 618, 5600 Fishers Lane, Rockville, MD 20852-9949.

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IT'S TIME TO RENEW ASAM MEMBERSHIPS FOR 1997!

It's that time of year again! Membership renewal notices for 1997 were mailed in October. ASAM committee members, committee chairs, and chapter leaders are required to renew their membership in order to maintain their posts throughout 1997. If you did not receive a notice, have questions, or want to renew by phone, simply call Theresa McAuliffe at the ASAM Membership Department (301/656-3920, extension 108). Remember, ASAM members receive significant discounts on the cost of conference registrations and publications, as well as a complimentary subscription to ASAM News.

Advertisements

Advertise in ASAM News

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For rates and deadlines, call the ASAM office:

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