DRUG ABUSE ADVISORY COMMITTEE MEETING

12/12-13/96

AGENDA FOR DRUG ABUSE ADVISORY COMMITTEE MEETING
Thursday, December 12, 1996
OPEN SESSION

Glaxo Wellcome Inc. NDA 20-711 Bupropion hydrochloride sustained release tablets as an aid for smoking cessation.

9:00 a.m. -	Greeting and Call to Order - Dr. Max Schneider, Chairman
9:05 a.m. -	Conflict of Interest Statement - Tracy Riley
9:10 a.m. -	Open public session
9:40 a.m. -	Sponsor Presentation:
	EFFICACY OF BUPROPION: Andy Johnston, Pharm.D., Senior Clinical Program Head, CNS Clinical Research
	SAFETY OF BUPROPION: John Asher, M.D., Senior Research Physician, CNS Clinical Research
	CONCLUSIONS: DR. Andy Johnston
10:40 a.m. -	Break
11:00 a.m. -	*FDA MEDICAL OFFICER PRESENTATION:* Celia Winchell, M.D., Drug Abuse Team Leader
11:15 a.m. -	Discussion of Question #1
12:00 a.m.	Lunch
1:00 p.m. -	Sponsor Presentation: *THE PLACE OF BUPROPION IN THE TREATMENT OF SMOKING CESSATION:*
	Richard D. Hurt, M.D., Director, Nicotine Dependence Research Center, Mayo Clinic
	Michael Fiore, M.D., M.P.H., Director, Center for Tobacco Research & Intervention, University of Wisconsin Medical School
1:30 p.m. -	FDA Presentation: *SPECIAL RISKS OF BUPROPION AND RISKS OF OTHER SMOKING CESSATION PRODUCTS:* Dr. Celia Winchell
1:45 p.m. -	Discussion of Question #2
2:15 p.m. -	*PRESENTATIONS ON DUAL NAME MARKETING:* Sponsor: Richard Kent, M.D., World Wide Director for Clinical Research
	FDA: Dr. Celia Winchell
2:45 p.m. -	Discussion of Questions #3 and #4

DRUG ABUSE ADVISORY COMMITTEE
Center for Drug Evaluation and Research

Questions for the Committee
December 12, 1996

NDA 20-711 Bupropion Sustained Release as an aid to Smoking Cessation Treatment

Questions for the Committee:

1. Does the Committee feel that there is substantial evidence of the safety and efficacy of bupropion SR in the smoking cessation indication?

2. What is the place of bupropion SR in the treatment of tobacco dependence?

3. Does the Committee agree that this product should be marketed with distinct and name, separate dosing recommendations, and unique labeling, distinct from Wellbutrin SR (which is marketed for depression) ?

   If so, do the proposed precautions taken to avoid inadvertent dual prescription appear adequate to protect the public?

4. Does the committee have any other recommendations with regard to the labeling of the product?

AGENDA FOR DRUG ABUSE ADVISORY COMMITTEE MEETING
Friday, December 13, 1996
OPEN SESSION

Pharmacia & Upjohn, Inc. NDA 20-714 Nicotrol Inhaler (nicotine inhalation system) for smoking cessation.

9:00 a.m. -	Greeting and Call to Order - Dr. Max Schneider, Chairman
9:05 a.m. -	Conflict of Interest Statement - Tracy Riley
9:10 a.m. -	Open public session
9:40 a.m. -	Sponsor Presentation:
	Introduction by Raymond E. Dann, Ph.D., Regulatory Affairs
	Background by Karl Olov Fagerstrom, Ph.D., Director, Scientific Information, Nicotine Replacement Therapy
	Phamacokinetics by Erik Lunell, M.D., Ph.D., Department of Clinical Pharmacology
	Efficacy, Dosing Rationale, and Safety by Mikael Frazon, Ph.D., Medical Department
	Abuse Potential by John R. Hughes, M.D., Professor of Psychiatry, University of Vermont
	Conclusion by Karl Olov Fagerstrom, Ph.D.
10:40 a.m. -	FDA Medical Officer Presentation of Pivotal Trials and Abuse Liability by Jack Longmire
11:00 a.m. -	Break
11:15 a.m. -	FDA Statistical Reviewer Presentation of Integrated Summary of Efficacy by Dr. Tom Permutt
11:30 a.m. -	FDA Pharmacokinetics Reviewer Presentation by Dr. Suresh Doddapaneni
11:45 a.m. -	Sponsor Reply
12:15 a.m. -	Lunch
1:15 p.m. -	Discussion of Questions for the Committee

DRUG ABUSE ADVISORY COMMITTEE
Center for Drug Evaluation and Research

Questions for the Committee
December 13, 1996

NDA 20-714 Nicotrol Inhaler (nicotine inhalation system)
for smoking cessation

1. Based on the information provided, does the committee consider the Nicotrol Inhaler to be effective?

2. Based on the information provided, does the committee consider the product to be of acceptable risk, used as directed?

3. Are labeling changes needed for this product ?

4. Should the sponsor study this product in a population with cardiac or pulmonary disease as a phase 4 commitment? If not, could the agency's concerns about use in this population be addressed sufficiently with language in the labeling?

DRUG ABUSE ADVISORY COMMITTEE
CENTER FOR DRUG EVALUATION AND RESEARCH

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DRUG ABUSE ADVISORY COMMITTEE
Center for Drug Evaluation and Research

Roster of Open Public Hearing Speakers
for December 12, 1996

Matthew Bars, M.D., Lung Diagnostics

Paula Kaiser, Patient Representative

Gregory Connolly, Director Massachusetts Tobacco Control Program

DRUG ABUSE ADVISORY COMMITTEE
Center for Drug Evaluation and Research

Roster of Open Public Hearing Speakers
for December 13, 1996

Louis W. Sullivan, M.D.

Al Munzer, M.D., Chief of Pulmonology , Adventist Hospital, Silver Spring MD

Scott D. Ballin, J.D., American Heart Association

ATTACHMENT 1

Glaxo Wellcome Inc. Consultants
December 12, 1996 meeting of the Drug Abuse Advisory Committee

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University of Pennsylvania Hospital
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Director, Palo Alto Center for Pulmonary Disease Prevention
Clinical Associate Professor, Division of Pulmonary & Critical Care Medicine - Stanford University School of Medicine
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Thomas Zink, M.D.
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DOCUMENTS CONNECTED WITH THIS MEETING
MUST BE REQUESTED FROM THE
FREEDOM OF INFORMATION (FOI) OFFICE

A written request specifying date of meeting, name of committee, and a description of the document(s) requested, may be mailed to:

Food and Drug Administration
Freedom of Information Staff
HFI-35, Room 12A-16
5600 Fishers Lane
Rockville, MD 20857
Telephone: 301-443-6310

or Faxed to:
301-443-1726

TRANSCRIPTS of the open session will be available from FOI 15 working days after the meeting. You may also purchase transcripts directly from the transcribing company.

SUMMARY MINUTES will be available from FOI approximately 90 days after the meeting. Please wait until this time period has elapsed before you place your order. Allow time for the minutes to be written, edited, approved, and photocopied for distribution. You may phone the Advisors and Consultants Staff at 301-443-5455 for status of minutes.

INVOICES are sent out monthly by the FOI Staff. If requested, FOI will inform you of fees in advance.

419

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETINGS: The following advisory committee meetings are announced:

Drug Abuse Advisory Committee

Date, time, and place. December 12 and 13, 1996, 8 a.m., Holiday Inn—Bethesda, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Open public hearing, December 12, 1996, 8 a.m. to 8:30 a.m., unless public participation does not last that long; open committee discussion, 8:30 a.m. to 5:30 p.m.; open public hearing, December 13, 1996, 8 a.m. to 8:30 a.m., unless public participation does not last that long; open committee discussion, 8:30 a.m. to 5:30 p.m.; Tracy Riley, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Drug Abuse Advisory Committee, code 12535. Please call the hotline for information concerning any possible changes.

General function of committee. The committee advises on the scientific and medical evaluation of information gathered by the Department of Health and Human Services and the Department of Justice on the safety, efficacy, and abuse potential of drugs and recommends actions to be taken on the marketing, investigation, and control of such drugs.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before November 28, 1996, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. On December 12, 1996, the committee will discuss NDA 20–711, bupropion hydrochloride sustained release tablets, Glaxo Wellcome Inc., as an aid for smoking cessation. On December 13, 1996, the committee will discuss NDA 20–724, Nicotrol® Inhaler (nicotine inhalation system), Pharmacia and Upjohn, Inc., as an aid for smoking cessation.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of the meeting(s) shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (a)(2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: November 15, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–29831 Filed 11–21–96; 8:45 am]

BILLING CODE 4160–01–F

Michael C. Fiore, M.D., M.P.H.
Associate Professor, Department of Medicine
Director, Center for Tobacco Research and Intervention
University of Wisconsin Medical School

My name is Michael C. Fiore. I am a practicing physician, specializing in internal medicine and preventive medicine. I continue to treat general internal medicine patients and am a specialist in treating tobacco addiction. Through my research and clinical activities, I have treated more than 5,000 patients for tobacco addiction over the last 15 years.

I am also an Associate Professor at the University of Wisconsin Medical School and serve as director of the UW Center for Tobacco Research and Intervention. Through a spectrum of research, clinical, educational, and policy activities, this national-know center is at the forefront of efforts to eliminate tobacco addiction from our society. Prior to joining the faculty of the University of Wisconsin, I served as a medical epidemiologist for the United States Office on Smoking and Health, Centers for Disease Control in Rockville. In this capacity, I contributed to national epidemiologic and policy issues including serving as a co-author on three Surgeon General's Reports on the Health Consequences of Smoking. I have served as Principal Investigator on the Bupropion Combination study and am speaking today as a consultant to Glaxo Wellcome, but the views expressed are my own.

Finally, I served as Chair of the Agency for Health Care Policy and Research (AHCPR) Clinical Practice Guideline on Smoking Cessation. This Guideline, released in April of this year, provides the new standard of care for treating tobacco addiction. Specifically, the Guideline established new criteria of appropriate pharmacotherapy for smoking cessation. Many on the panel here today are aware that the Cessation Guideline recommends that every patient who attempts to quit smoking should use a nicotine replacement product on every quit attempt in the absence of a major contraindication to that use. The Guideline panel did not have information on the effectiveness of Bupropion as an aid to smoking cessation at the time of our systematic analysis of pharmacotherapeutic options and therefore, did not comment at that time.

First, I would like to address some of the public health reasons why I believe Bupropion has demonstrated sufficient efficacy to warrant it's use as a primary pharmacotherapy for smoking cessation. I know I don't need to convince anyone on this panel of the uniquely deadly impact of tobacco on the health of Americans. Today, one out of every five deaths are directly caused by tobacco use - more than 42,000 per year. In addition to this mortality burden, tobacco impacts the health care system through a tremendous morbidity burden, result in acute and chronic illnesses that cost the health care system more than 50 billion dollars each year.

It is because of this extraordinary morbidity, mortality, and cost burden that the AHCPR Smoking Cessation Clinical Practice Guideline panel now urges that the vital signs (BP, Pulse, and Temperature) be expanded such that tobacco use be asked and documented for every patient at every health care visit, regardless of what brings the patient to the clinic.

Repeated surveys of smoking in the United States have documented that approximately 70% of smokers want to quit smoking and have made at least one unsuccessful attempt to quit. In fact, each year, of the approximately 50 million smokers in the United States, almost 20 million, try to quit. Of these, it is estimated that only 6.5% of these will succeed in maintaining long term abstinence from this deadly drug. These discouraging statistics along with the enormous health burdens mandate additional action to promote smoking cessation.

The AHCPR Guideline on Smoking Cessation, highlight that, from a public health perspective, no group rival physicians in terms of their unique access to cigarette smokers. Each year, 70% of smokers visit a primary care physician. Therefore, the AHCPR Guideline urges that every clinician at every visit identify the tobacco use status of each patient, document that status, and provide a brief intervention including pharmacotherapy to patients who use tobacco.

Unfortunately, physicians in 1996 have limited options in treating tobacco dependence. The only medications currently approved and demonstrated effective by the AHCPR panel are nicotine replacement therapies. New treatment options are essential and my review of the Bupropion data presented today leads me to two key conclusions:

1. It is safe medication for patients for smoking cessation when used appropriately.
2. It achieves cessation rates at least comparable to our current gold standard, the nicotine patch.

I'd like to make some estimates of the public health potential of Bupropion. Current statistics demonstrate that approximately 20 million of the 50 million smokers in the United States today make a quit attempt each year. Of the 20 million who try to quit, about 1.3 million (6.5% of those trying), succeed.

The results of the dose-response study demonstrate that Bupropion results in long term (one year) smoking cessation rates approaching 23%. Previous research on smoking cessation has demonstrated that the success rates of smoking cessation clinical trials are rarely achieved in "real-world" primary care practices. Calling on our experience with the nicotine patch, I would estimate that, in such "real-world" settings, the long term success rates would be halved, from 23% to 12% in actual practice.

What would the public health impact be of a 12% success rate? Well, among the 20 million individuals who try to quit each year, clearly most will not use Bupropion. However, using the nicotine patch again as a model, I believe a realistic penetration rate for this medication would be that about one-eight (12.5%) of smokers may try to quit using this method each year. Multiplying this 12.5% use rate by the 20 million individuals who try to quit each year will result in, potentially 2.5 million users each year. If these 2.5 million users achieved the predicted primary care success rate of about 12%, the public health impact would be 300,000 new quitters each year! From a public heath point of view, the impact of those additional 300,000 quitters each year would be enormous. This could result in thousands of lives saved each year.

Well, I would like to end by reiterating three points:

First, Bupropion appears to be a safe agent for smoking cessation.

Second, Bupropion achieves success rates at least as equal to the current gold standard, the nicotine patch.

Third, based on these two findings, use of this drug as a first line agent is, in my view, both appropriate and warranted.

The impact of smoking on our society continues to be enormous. We must seize upon efforts to move both smokers and clinicians alike towards safe and effective treatments such as Bupropion to promote smoking cessation.

Thank you very much.

ASAM American Society of Addiction Medicine
4601 NORTH PARK AVENUE • UPPER ARCADE, SUITE 101 • CHEVY CHASE, MD 20815

December 10, 1996

Tracy Riley
Executive Secretary
Drug Abuse Advisory Committee
Center for Drug Evaluation and Research
(HFD-21)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Marketing of therapeutic nicotine products

Dear Ms Riley:

I am concerned that pharmaceutical companies marketing therapeutic nicotine products are focusing their energies on winning market share from each other instead of seeking to expand the market for their products.

Therapeutic nicotine products are in competition with tobacco products. The nicotine market is huge when thought of in terms of all who use nicotine, whatever the form. Most people who smoke want to stop. This is a very robust finding in every survey of every population of smokers with which I am familiar. It even applies to adolescents who smoke and to people with alcohol dependence who smoke. The overall nicotine market is the major market opportunity for therapeutic nicotine products.

Each therapeutic product on the market has proven its worth to the Food and Drug Administration, yet the marketing of at least one product has misused the data on which FDA based its decisions. Specifically, it is inappropriate for marketing materials to dredge up details from clinical trials for product comparisons. The clinical trials utilize specific protocols. These protocols have become the basis for labeling only because they represent the only specific use data

available to the FDA. In actual practice, clinicians and consumers use these products with flexibility. Advertising which relies on fixed schedule protocols is misplaced. Such fixed schedules are important scientifically for establishing efficacy, but they do not necessarily represent sound clinical practice.

I urge the Committee and the FDA to encourage the pharmaceutical companies which market therapeutic nicotine products to focus their marketing energies on expanding the market rather than on grabbing market share of a tiny market from each other. The real public health concern is not any minor differences which might exist between one therapeutic product and another. The real public health concern is the major differences which exist between tobacco products and therapeutic nicotine products.

Respectfully submitted,

John Slade, M.D.
Chair
Committee on Nicotine Dependence

ASAM
American Society of
Addiction Medicine

MEMORANDUM

DATE: December 12, 1996

TO: FDA Drug Abuse Advisory Committee

FROM: American Society of Addiction Medicine (ASAM)
(Dr. James F. Callahan, Executive Vice President and Chief Executive Officer)

SUBJ: NDA 20-711 Bupropion hydrochloride sustained release tablets as an aid for managing nicotine dependence (Glaxo Wellcome, Inc.)

On behalf of the American Society of Addiction Medicine (ASAM), I speak in support of the New Drug Application (NDA) for bupropion hydrochloride sustained release tablets as an aid for managing nicotine dependence.

ASAM is the national medical specialty society of 3,300 physicians dedicated to prevention, research, and treatment of alcohol, nicotine and other drug dependence and addictive diseases. ASAM has a seat in and is a voting member of the American Medical Association (AMA) House of Delegates; has a Committee on Nicotine Dependence and treatment; annually sponsors a national scientific and clinical conference on treatment of nicotine dependence; and has published a public policy statement on "Nicotine Dependence and Tobacco."

Nicotine dependence is the most common form of chemical dependence in the United States. Cigarettes annually cause an enormous burden of illness, disability and death, more than 400,000 premature deaths in the U.S. and 3,000,000 worldwide.

Therefore, in addition to other public health actions, there is an urgent need for effective pharmacologic approaches to managing nicotine dependence.

4601 NORTH PARK AVENUE • ARCADE SUITE 101 • CHEVY CHASE, MD 20815-4520
(301) 656-3920 FAX (301) 656-3815

ASAM applauds the FDA's timely response in the New Drug Application for bupropion, the first non-nicotine pharmacologic treatment for managing nicotine dependence. From the time when the first bupropion research project was presented at ASAM's scientific conference four years ago, we have hoped for the approval of this new drug for managing nicotine dependence. We urge approval, so that clinicians may have a new and effective medication for their patients. I have attached a copy of the ASAM Public Policy Statement for your information.

ATT: *Nicotine Dependence and Tobacco*

K:\HOME\ADMIN\NICOTINE\FDA-TEST.D12

AMERICAN SOCIETY OF ADDICTION MEDICINE, INC.

Public Policy Statement
on
Nicotine Dependence and Tobacco

Background

Nicotine is the psychoactive drug in tobacco. Regular use of tobacco products leads to addiction in a high proportion of users.

Nicotine dependence is the most common form of chemical dependence in the United States. This addiction is especially prevalent among those who suffer from alcoholism and from other drug dependencies.

Nicotine dependence most often begins as a pediatric disease. In 1994, four million young people, aged 12-17 years, were current users of cigarettes. Three thousand youth become regular users each day, one-third of whom will eventually die from a cigarette-caused disease.

The nicotine addiction epidemic is fueled in part by the low price of tobacco products, their ready availability to the underage (despite laws to the contrary), and the enormous marketing campaigns for these products (campaigns that are often very seductive and attractive to the young). In 1993, the cigarette industry spent $6.03 billion, or 25 cents per pack, on marketing.

Cigarettes cause an enormous burden of illness, disability and death. In 1989, the cigarette caused more than 400,000 premature deaths in the United States and more than 3 million worldwide.

Smokeless tobacco use is epidemic among the young. Smokeless tobacco products, along with cigars and pipe tobacco, are causes of nicotine addiction and cancer, among other serious problems. Cigar smoke has been shown to cause lung cancer, emphysema and heart disease among the many users who inhale the smoke.

The general public is aware that tobacco use is harmful, but it seriously underestimates the magnitude of the harm which tobacco causes.

Nonsmokers, too, are harmed by tobacco use. Nonsmokers may themselves become ill with lung cancer, heart disease, lower respiratory ailments, worsening of asthma and other problems through exposure to environmental tobacco smoke. They suffer through the illnesses and premature deaths of family members, friends and associates. They also share unwittingly in the economic costs of tobacco use because of higher insurance and medical care costs.

Becoming abstinent from tobacco has been shown to have substantial beneficial effects on health and longevity. The treatment of nicotine addiction reduces the complications of this addiction. Many who successfully recover from another addiction die from a complication of nicotine addiction. The widespread notion that nicotine dependence is best left untreated during the course of treatment for other drug dependencies lacks empiric support.

Although the medical profession has traditionally viewed tobacco use as a risk factor for other diseases, instead of a primary problem in itself, this approach has impeded, rather than promoted, the development of optimal treatment methods for patients addicted to nicotine. 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.

Policy Recommendations

The American Society of Addiction Medicine advocates and supports the development of policies and programs which promote the prevention and treatment of nicotine addiction. These include, but are not limited to, the following:

1. **The availability of tobacco products to the young should be controlled through the establishment of an enforced, national minimum age of 21 years for purchase of all tobacco products and the requirement that all sales of tobacco products be face to face encounters, eliminating vending machines, self-service and mail order sales. Efforts to reduce tobacco sales to minors should reserve punitive approaches to manufacturers, distributors and merchants, and should not include measures that penalize underage possession or use of tobacco products. Punishment of the user perpetuates a counterproductive judicial approach. Minors who use tobacco products should instead be referred for educational or clinical services, as indicated.**

2. **Governmental policies regarding tobacco should be changed in several ways. These include:**

   a) **Assigning the regulation of all nicotine-containing products intended for human consumption to the Food and Drug Administration. In particular, ASAM vigorously supports the proposal made by the FDA in the Federal Register of August 11, 1995 to regulate cigarettes and smokeless tobacco products as nicotine delivery devices.**

   b) **Requiring tobacco product manufacturers to publish and publicize the ingredients used in each brand they offer to the public and to publish and publicize the levels of toxic substances, including nicotine, that customers who consume each such product may reasonably expect to ingest.**

   c) **Requiring the inclusion of package inserts in each tobacco product sold to a consumer. Such inserts would contain useful information about the harm of tobacco use, the benefits of stopping, and advice on how to stop.**

   d) **Strengthening the warning labels on cigarettes and smokeless tobacco and extending the warning label system to all other tobacco products so that the warnings are much more visible, easier to understand, and explicitly describe the risks of addiction, disease and death from use of these products.**

   e) **Enforcing the ban against cigarette advertising in broadcast media by directing the Justice Department to take action against cigarette brand promotions and sponsorships in motorsports.**

f) Eliminating all advertising and other promotional activities for nicotine-containing tobacco products, including mandating that all packaging for tobacco products be plain packaging, in order to eliminate the allure provided by package design and brand-associated symbols.

g) Adopting measures already in place in Ontario which prohibit pharmacies and stores with pharmacy departments from selling tobacco products.

h) Supporting research and public health efforts funded through the various branches of government, including the Department of Defense, the NIH, CDC, SAMHSA, and state initiatives that contribute to (1) an understanding of nicotine addiction, its treatment and its prevention, and (2) controlling the epidemic, including research and programmatic assistance in understanding and dealing with the profound clinical interrelationships among nicotine, alcohol and other drugs of abuse.

i) Encouraging politicians to refuse to accept support from tobacco companies so that they can more easily work to control the epidemic caused by tobacco.

j) Eliminating subsidies and all other forms of governmental assistance which encourage the production or exportation of tobacco and tobacco products or which have the effect of establishing a minimum nicotine level in leaf tobacco.

k) Funding transition programs for displaced workers from excise taxes on tobacco products when jobs now in the tobacco industry are eventually shifted to other parts of the economy as a result of the above and other measures.

l) Increasing substantially state and federal taxes on tobacco products and assigning a portion of the revenue generated from increased taxes to fund sustained, integrated, multifaceted public health programs to reduce tobacco consumption.

m) Eliminating tobacco as an export crop and eliminating tobacco products as export products from the United States (so that this country does not contribute to the tobacco problems faced by any other nation), and replacing government assistance for tobacco product exports with the export of medical and public health knowledge about tobacco and about how to control the tobacco epidemic.

n) Requiring alternative designs to make cigarettes fire-safe, since these products are the leading cause of death in household fires.

3. Public education about tobacco should be enhanced by additional measures, including:

a) Establishing primary and secondary schools as tobacco-free zones with clinical support made available as a benefit of enrollment or employment for those students and staff who want assistance in dealing with nicotine dependence.

b) Teaching of youth in the schools about the risks of addiction, disease and death from tobacco use and about the cynical efforts of the tobacco industry to recruit new customers from among their peers.

c) Countermarketing tobacco products, including advertisements and other efforts, to offset the seduction of tobacco advertising imagery and to educate the public about the hazards of tobacco and about methods of quitting or of not starting tobacco use.

4. Research, professional education, and clinical expertise in the areas of nicotine dependence should receive increased emphasis through the following measures:

a) Promoting research in universities and other institutions into the causes, prevention, and treatment of nicotine dependence.

b) Training all health professionals to regard nicotine dependence as a primary medical problem including training in the management of nicotine dependence on the part of physician specialists in addiction medicine, primary care physicians, clinical psychologists, and all drug and alcohol counselors. This training should also include information on the ways the tobacco industry perpetuates the epidemic and undermines efforts aimed at reducing the problem and on ways health care professionals can help counter these influences.

c) Teaching about the dependency process and about the management of nicotine dependence in CME courses and other professional education programs.

d) Teaching that nicotine dependence needs to be diagnosed and treated along with other drug dependencies.

e) Exploring mechanisms for third party reimbursement for the treatment of nicotine dependence by qualified health professionals who use clinically recognized methods.

f) Refusal of any funding from the tobacco industry and its subsidiaries by medical schools, other research institutions and individual researchers to avoid giving tobacco companies an appearance of credibility.

g) Encouraging all institutions involved in health care to divest from the tobacco industry since investments in this industry are profitable only to the extent that measures to control the epidemic fail.

5. Smoke-free policies should be implemented in all workplaces and places of public accommodation, including all health-care facilities.

6. Health care delivery systems should provide treatment of nicotine dependence for their patients.

7. Legal action against the tobacco industry should be supported, including law suits by states, private insurers and others seeking to recover money spent on medical care of tobacco-caused disease, consumer protection actions seeking to better inform the public about

tobacco or to stop industry practices which harm the public health, and product liability suits brought by individuals who have been harmed by tobacco products.

8. ASAM should actively participate in a liaison network with other groups on issues of mutual interest related to tobacco.

Adopted By ASAM Board of Directors, 4/20/88
Amended By ASAM Board of Directors, 9/25/89
Amended By ASAM Board of Directors, 4/17/96, 10/6/96

ASAM
American Society of
Addiction Medicine

MEMORANDUM

DATE: December 13, 1996

TO: FDA Drug Abuse Advisory Committee

FROM: American Society of Addiction Medicine (ASAM)
(Dr. James F. Callahan, Executive Vice President and Chief Executive Officer)

SUBJ: NDA 20-724 Nicotrol Inhaler: Nicotine inhalation system as an aid for managing nicotine dependence (Pharmacia and Upjohn, Inc.)

On behalf of the American Society of Addiction Medicine (ASAM), I speak in support of the New Drug Application (NDA) for the nicotrol inhaler (nicotine inhalation system) as an aid for managing nicotine dependence.

ASAM is the national medical specialty society of 3,300 physicians dedicated to prevention, research, and treatment of alcohol, nicotine and other drug dependence and addictive diseases. ASAM has a seat in and is a voting member of the American Medical Association (AMA) House of Delegates; has a Committee on Nicotine Dependence and treatment; annually sponsors a national scientific and clinical conference on treatment of nicotine dependence; and has published a public policy statement on "Nicotine Dependence and Tobacco."

Nicotine dependence is the most common form of chemical dependence in the United States. Cigarettes annually cause an enormous burden of illness, disability and death, more than 400,000 premature deaths in the U.S. and 3,000,000 worldwide.

Therefore, in addition to other public health actions, there is an urgent need for effective pharmacologic approaches to managing nicotine dependence.

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(301) 656-3920 FAX (301) 656-3815

The nicotine inhaler will give primary care physicians and other clinicians a fourth pharmacologic tool to assist their patients. ASAM recommends that in prescribing the nicotine inhaler, clinicians should buttress this new form of nicotine replacement therapy with effective behavioral & other treatments of the addiction. The Agency for Health Care Policy and Research's clinical practice guideline, *Smoking Cessation* (1996), offers primary care and tobacco program specialists recommendations in this regard.

ASAM recommends approval of the nicotrol inhaler. For your information, I have attached a copy of the ASAM public policy statement on "Nicotine Dependence and Tobacco."

ATT: *Nicotine Dependence and Tobacco*

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AMERICAN SOCIETY OF ADDICTION MEDICINE, INC.

Public Policy Statement
on
Nicotine Dependence and Tobacco

Background

Nicotine is the psychoactive drug in tobacco. Regular use of tobacco products leads to addiction in a high proportion of users.

Nicotine dependence is the most common form of chemical dependence in the United States. This addiction is especially prevalent among those who suffer from alcoholism and from other drug dependencies.

Nicotine dependence most often begins as a pediatric disease. In 1994, four million young people, aged 12-17 years, were current users of cigarettes. Three thousand youth become regular users each day, one-third of whom will eventually die from a cigarette-caused disease.

The nicotine addiction epidemic is fueled in part by the low price of tobacco products, their ready availability to the underage (despite laws to the contrary), and the enormous marketing campaigns for these products (campaigns that are often very seductive and attractive to the young). In 1993, the cigarette industry spent $6.03 billion, or 25 cents per pack, on marketing.

Cigarettes cause an enormous burden of illness, disability and death. In 1989, the cigarette caused more than 400,000 premature deaths in the United States and more than 3 million worldwide.

Smokeless tobacco use is epidemic among the young. Smokeless tobacco products, along with cigars and pipe tobacco, are causes of nicotine addiction and cancer, among other serious problems. Cigar smoke has been shown to cause lung cancer, emphysema and heart disease among the many users who inhale the smoke.

The general public is aware that tobacco use is harmful, but it seriously underestimates the magnitude of the harm which tobacco causes.

Nonsmokers, too, are harmed by tobacco use. Nonsmokers may themselves become ill with lung cancer, heart disease, lower respiratory ailments, worsening of asthma and other problems through exposure to environmental tobacco smoke. They suffer through the illnesses and premature deaths of family members, friends and associates. They also share unwittingly in the economic costs of tobacco use because of higher insurance and medical care costs.

Becoming abstinent from tobacco has been shown to have substantial beneficial effects on health and longevity. The treatment of nicotine addiction reduces the complications of this addiction. Many who successfully recover from another addiction die from a complication of nicotine addiction. The widespread notion that nicotine dependence is best left untreated during the course of treatment for other drug dependencies lacks empiric support.

Although the medical profession has traditionally viewed tobacco use as a risk factor for other diseases, instead of a primary problem in itself, this approach has impeded, rather than promoted, the development of optimal treatment methods for patients addicted to nicotine. 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.

Policy Recommendations

The American Society of Addiction Medicine advocates and supports the development of policies and programs which promote the prevention and treatment of nicotine addiction. These include, but are not limited to, the following:

1. **The availability of tobacco products to the young should be controlled through the establishment of an enforced, national minimum age of 21 years for purchase of all tobacco products and the requirement that all sales of tobacco products be face to face encounters, eliminating vending machines, self-service and mail order sales. Efforts to reduce tobacco sales to minors should reserve punitive approaches to manufacturers, distributors and merchants, and should not include measures that penalize underage possession or use of tobacco products. Punishment of the user perpetuates a counterproductive judicial approach. Minors who use tobacco products should instead be referred for educational or clinical services, as indicated.**

2. **Governmental policies regarding tobacco should be changed in several ways. These include:**

   a) **Assigning the regulation of all nicotine-containing products intended for human consumption to the Food and Drug Administration. In particular, ASAM vigorously supports the proposal made by the FDA in the Federal Register of August 11, 1995 to regulate cigarettes and smokeless tobacco products as nicotine delivery devices.**

   b) **Requiring tobacco product manufacturers to publish and publicize the ingredients used in each brand they offer to the public and to publish and publicize the levels of toxic substances, including nicotine, that customers who consume each such product may reasonably expect to ingest.**

   c) **Requiring the inclusion of package inserts in each tobacco product sold to a consumer. Such inserts would contain useful information about the harm of tobacco use, the benefits of stopping, and advice on how to stop.**

   d) **Strengthening the warning labels on cigarettes and smokeless tobacco and extending the warning label system to all other tobacco products so that the warnings are much more visible, easier to understand, and explicitly describe the risks of addiction, disease and death from use of these products.**

   e) **Enforcing the ban against cigarette advertising in broadcast media by directing the Justice Department to take action against cigarette brand promotions and sponsorships in motorsports.**

f) **Eliminating all advertising and other promotional activities for nicotine-containing tobacco products, including mandating that all packaging for tobacco products be plain packaging, in order to eliminate the allure provided by package design and brand-associated symbols.**

g) **Adopting measures already in place in Ontario which prohibit pharmacies and stores with pharmacy departments from selling tobacco products.**

h) **Supporting research and public health efforts funded through the various branches of government, including the Department of Defense, the NIH, CDC, SAMHSA, and state initiatives that contribute to (1) an understanding of nicotine addiction, its treatment and its prevention, and (2) controlling the epidemic, including research and programmatic assistance in understanding and dealing with the profound clinical interrelationships among nicotine, alcohol and other drugs of abuse.**

i) **Encouraging politicians to refuse to accept support from tobacco companies so that they can more easily work to control the epidemic caused by tobacco.**

j) **Eliminating subsidies and all other forms of governmental assistance which encourage the production or exportation of tobacco and tobacco products or which have the effect of establishing a minimum nicotine level in leaf tobacco.**

k) **Funding transition programs for displaced workers from excise taxes on tobacco products when jobs now in the tobacco industry are eventually shifted to other parts of the economy as a result of the above and other measures.**

l) **Increasing substantially state and federal taxes on tobacco products and assigning a portion of the revenue generated from increased taxes to fund sustained, integrated, multifaceted public health programs to reduce tobacco consumption.**

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n) **Requiring alternative designs to make cigarettes fire-safe, since these products are the leading cause of death in household fires.**

3. **Public education about tobacco should be enhanced by additional measures, including:**

a) **Establishing primary and secondary schools as tobacco-free zones with clinical support made available as a benefit of enrollment or employment for those students and staff who want assistance in dealing with nicotine dependence.**

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tobacco or to stop industry practices which harm the public health, and product liability suits brought by individuals who have been harmed by tobacco products.

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Adopted By ASAM Board of Directors, 4/20/88
Amended By ASAM Board of Directors, 9/25/89
Amended By ASAM Board of Directors, 4/17/96, 10/6/96

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Office of
Public Affairs

December 13, 1996

**Statement of the American Heart Association
Concerning Smoking Cessation Products and Devices
Before the FDA Drug Abuse Advisory Committee**

Cardiovascular diseases and stroke are this nation's number one and number three leading causes of death, accounting for close to 950,000 deaths each year. Tobacco use is this nation's single most preventable cause of death and is a major risk factor for cardiovascular diseases and stroke.

The American Heart Association has for decades been involved in a number of public education, research and policy activities that are designed to discourage and prevent the use of tobacco products. This includes efforts to assist the forty million Americans who still smoke to quit their addiction.

One way of accomplishing such assistance is through the use of smoking cessation drugs and devices. The American Heart Association has indicated in past statements that it is in support of the use of such products by the American public as part of a comprehensive smoking cessation effort. We believe, however, that it is critical that such drugs and devices be carefully and fully reviewed by the Food and Drug Administration for efficacy, safety, labeling as well as marketing. This also includes consideration of educational materials and efforts to fully assist the smoker with the most useful and practical information that will enhance quit rates. The product being reviewed today by the Advisory Committee falls into such a class of products.

As the Drug Abuse Advisory Committee continues to review a variety of smoking cessation drugs and devices, it should be equally concerned about a myriad of nicotine delivery products on the market that have not been adequately reviewed. These products may lead the American public to believe that such products are safer, less addictive and a way to switch down on tar and nicotine levels and eventually quit. These products include not only cigarettes and other forms of tobacco, but also such novel new products as RJR's Eclipse, the cigarette that heats tobacco, but does not burn it.

While we have been supportive of smoking cessation drugs, devices and products that have been reviewed and approved by the FDA, we have been equally critical of efforts by some nonpharmaceutical companies to bypass the FDA review and approval process. We strongly oppose marketing smoking cessation products that have never been subjected to any scientific evaluation and for which there is any documentation of efficacy and safety.

Testimony of

Gregory N. Connolly, DMD, MPH,

Director

Tobacco Control Program, Massachusetts Department of Public Health,
Boston, Massachusetts

before
the Food and Drug Administration's Drug Abuse Advisory Committee

December 12, 1996.

My name is Gregory Connolly, I am Director of the Massachusetts Department of Public Health's Tobacco Control Program. I am a graduate of Holy Cross , Tufts University School of Dental Medicine, the Harvard School of Public Health. I have worked in the area of tobacco and health for over 14 years and have extensive experience and training in the area of smoking cessation and have published a number of articles on the topic.

The Massachusetts Tobacco Control Program is a 35 million dollar state agency that which has achieved considerable success in curbing smoking in our state since its inception in 1993. Over the past 3 years cigarette consumption has fallen 18% in Massachusetts almost 4 times the national average. Our program operates a 12 million dollar paid counter advertising campaign that devotes approximately 25% of its dollars to educating the adult smoker about the dangers of tobacco use. We also fund over 60 local public health programs to provide smoking cessation services to adult smokers and fund local health departments to pass and enforce Clean In-Door Air laws which alter the social environment resulting in many smokers either cutting down or quitting entirely.

I have also worked closely with the Federal Food and Drug Administration over the past few years in developing the new regulation that declares cigarettes and smokeless tobacco products as medical devises and will continue to work closely with the agency as it implements the final rule.

The Public Health community welcomed the move of nicotine replacement therapy from the status of prescription drug to over the counter medication. We had three expectations when the switch occurred. First the substantial dollars would be devoted to antitobacco advertising and the messages would broadly address the dangers dangers of smoking and greatly expand the pool of smokers who were attempting to quit.. Resources would finally be available to counter tobacco advertising. Second, that public health workers would have an additional tool to help smokers quit and that the manufacturers of these products would aggressively outreach to public health agencies to ensure that NRT was integrated within their programs. Finally, that OTC status would lower price, make the product more accessible and resulting in overall increase in its use.

For the past few months I have closely monitored the advertising and marketing of patches and gums and am disappointed in how the manufacturers have performed. I would like to share some of my findings and concerns with the Committee.. First, I am disappointed that the advertising has focused narrowly on smokers who are in the action phase and not on a larger strategy that would move people from precontemplation to contemplation and then action. A recent quote from Jordan McGraph, a creative director for Nicorette/Nicoderm advertising agency provides insight. He stated in a September USA Today article "we aren't here to preach the horrors of smoking we're here to advertise this product is available to smokers once they have convinced themselves that it is time to quit." I disagree with this strategy. In Massachusetts when we first began our ad campaign three years ago, we found the number of persons in the action phase to be

relatively small and launched heavy advertising first directed to precontemplaters later to contemplaters and we saw the number of persons in the action phase jump. Over time we achieved high quit rates particularly among the 18-30 year old market. It would be wise for manufacturers of NRT to broaden messages about the dangers of smoking or about the harm second hand smoke can cause to a person around the them. These messages should be phased in and run in parallel to messages that address issues of safety and efficacy of the product. One manufacture has begun to do this with the promotion the Great American Smokeout but I believe much much more can be done.

My second concern is that some of the messages may encourage misuse of the product. A recent television ad that ran in August featured an actress that stated that when she had a craving she would just pop gum in her mouth. This type of advertising my imply to the smoker that the gum is for only intermittant use to stop a craving This is not an appropriate message and may result in relapse or combined use of gum and smoking. I contacted the company that was responsible for the ad, raised the question and they voluntarily withdrew. There is a need for continued monitoring of the advertising by an independent agency.

A third concern is over advertising that promotes one brand against another. A recent promotional ad used a visual graph to imply thier brand was more effective than another . The graph represented two different studies that could not allow for adequate comparison between either brand. In our focus testing we found confusion among smokers about the safety and efficacy of NRT. Advertising that pits one product against

the other can only lead to further confusion and rejection by smokers of nicotine replacement therapy. Manufacturers should refrain from this type of advertising.

A final concern is that manufacturers who provide support services for persons s should evaluate the use, cost and effectiveness and this should be done by an independent entity.

In summary, I would strongly recommend that the FDA require manufacturers to their message about smoking and health work much more closely with state and local public health agencies and refrain from advertising that may promote misuse or no use of NRT.

As the Advisory Committee considers new forms of nicotine replacement therapy careful assess of current marketing practices should be done. Short term commercial interests should not take not take precedence over the long term goal of promting use of NRT and reducing tobacco use.

Conflict of Interest Statement

I am not a consultant to,. an investigator for, or a spckesman of any pharmaceutical company. I hold no finnancial interest in any NRT product

Ladies and Gentlemen, I wish to thank you for the opportunity to address you today. My name is Matthew Bars and I am a Master's level Clinical Psychologist specializing in nicotine dependence. I have treated smokers since 1980 in a private practice medical office setting. Prescriptions are written by our pulmonologists after intensive assessment and evaluation of each individual patient. I have clinical experience with multiple treatment modalities treating over ten thousand smokers.

I first became aware of Dr. Linda Ferry's work on Bupropion and tobacco dependence about four years ago. Since then we have treated over one thousand smoking patients using Bupropion. We have found this medication to be a safe, effective, and unique medication which successfully addresses the addiction to nicotine. Bupropion can be used the way smokers actually quit, that is, with stops and starts, successes and relapses. Consequently, unlike nicotine replacement therapies, with Bupropion a recovering smoker can continue pharmacotherapy if he or she suffers a relapse back to tobacco use.

Furthermore, we have observed a unique response profile to Bupropion. Smokers report tobacco taste perversion (cigarettes tasting bad); tobacco anhedonia (decrease or absence of tobacco pleasure) and changes in smoking topology (fewer puffs per cigarette, decreased puff volume). We have also observed that Bupropion increases the smoker's motivation to quit, moving them through the stages of readiness to change: Precontemplation to contemplation to preparation and action. These anecdotal observations have been reported by other clinicians (Dr. Linda Ferry, Personal Communication, 1996). Stated simply, Bupropion increases quit rates and decreases tobacco withdrawal symptoms in ways currently approved therapies do not.

We have observed that Bupropion can work in conjugation with nicotine patches, nicotine polacrilex gum, and the nicotine nasal spray. Bupropion can work where nicotine replacement has not succeeded. Others will address the specifics of Bupropion's effectiveness in double blind, placebo controlled, multicentered studies. Suffice is to say, that Bupropion works in successfully treating addicted smokers.

I urge this committee while reviewing any risk-benefit consideration to remember that over 1,000 Americans will die today, and every day, as the result of their tobacco addiction. The tobacco pandemic and the resulting costs in morbidity and mortality demands aggressive medical intervention. Nicotine replacement therapies are effective medications for treating tobacco dependence. However, nicotine therapies do not help every smoker or even a majority of smokers. Futhermore, there is data that OTC Nicotine replacement products are effective with less than ten percent of the population. Similarly, we have data that some smokers can not stop with nicotine replacement therapies. We see it every day. Consequently, clinicians must be afforded the opportunity to use Bupropion as a first line therapy.

There is an old saying that if the only tool you have is a hammer, every problem looks like a nail. Clinicians need additional tools to successfully treat tobacco dependent individuals. Bupropion represents another effective tool, with a unique mechanism of action, for treating the addiction to tobacco. Physicians are fully capable of utilizing their clinical judgement in the prescribing of this medication. I respectfully request and strongly urge this committee recommend Bupropion's approval as an first line therapeutic aid to smoking cessation. Thank you.

Good Morning, My name is Paula Kaiser and I am from Hackensack, New Jersey and I stopped smoking with Wellbutrin almost 2 years ago. I know it helped me while nicotine patches did not. With Wellbutrin I found it easier to stop. I used Wellbutrin for about 8 weeks and noticed I was calmer, less uptight and found it easier to resist the urges to smoke that I experienced with the nicotine patches. Wellbutrin took the edge off my tobacco withdrawal. I had no side effects or problems using the medication.

The weekly Behavioral support I received and the medical tests showing how smoking had damaged my lungs and made them precancerous, was very helpful in motivating me to quit and remaining free from cigarettes. This helped me realize that smoking was serious business and it could kill me.

I do not believe that I would have stopped smoking without the benefit of Wellbutrin. Wellbutrin is a great alternative in helping smokers stop and should be made available to more smokers. The FDA should approve the use of Wellbutrin for helping smokers quit. Thank you.

American Heart Association
Fighting Heart Disease and Stroke

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December 6, 1996

Tracy Riley
Center for Drug Evaluation and Research
HFD-21
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Via fax: (301) 443-0699

Dear Ms. Riley:

On December 13, 1996, during the open public hearing the American Heart Association would like to present for seven minutes before the Drug Abuse Advisory Committee. The committee will discuss the Nicotrol Inhaler system at this time. I will represent the AHA and will discuss nicotine containing and smoking cessation products. Please contact Jennifer Johnson at (202) 822-9380 if you have any questions.

Sincerely,

Scott D. Ballin J.D.
Vice President and Legislative Counsel

PinneyAssociates

Health Consulting
Issues Management
Market Research

November 27, 1996

Tracy Riley
Center for Drug Evaluation and Research (HFD-21)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Ms. Riley:

I am writing on behalf of Dr. Al Munzer, Chief of Pulmonology at Adventist Hospital in Silver Spring, MD. Dr. Munzer would like to make a brief statement during the open public hearing portion of the December 13 meeting of FDA's Drug Abuse Advisory Committee discussing the Nicotrol Inhaler. Dr. Munzer is a former president of the American Lung Association, and has previously spoken at an FDA advisory committee open public hearing in September 1995 in support of FDA approval of the Rx-to-OTC switch of Nicorette nicotine gum.

Dr. Munzer's statement will be in general support of FDA approval of the Nicotrol Inhaler, but will express some concerns regarding the abuse liability and possible misuse of the product. Specifically, Dr. Munzer will reiterate general principles for consideration of nicotine replacement products, as presented by Ms. Fran DuMelle of the Coalition on Smoking OR Health at the April 1996 meeting of FDA's Drug Abuse and Nonprescription Drugs Advisory Committees. The time required for Dr. Munzer's remarks will be approximately 5 minutes.

We will be providing a more detailed copy of Dr. Munzer's proposed presentation in advance of the Dec. 13 meeting, probably during the first week of December. Please do not hesitate to contact me if you have any questions regarding this request.

Sincerely,

Tula Michaelides

Tula Michaelides

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