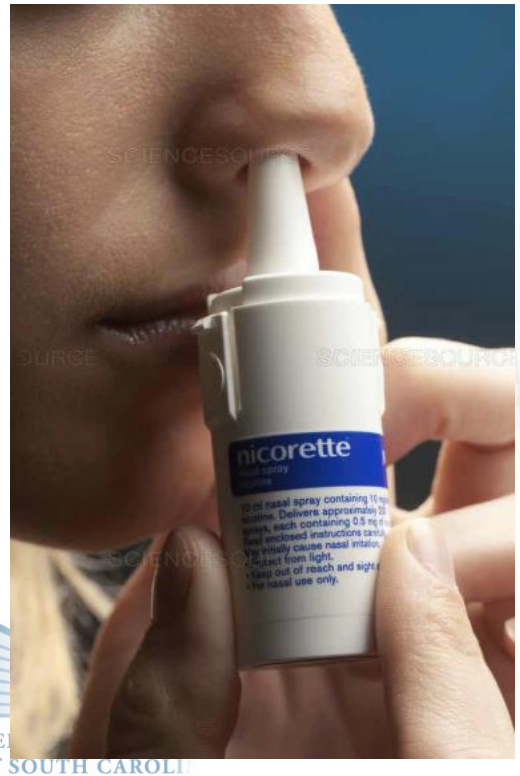
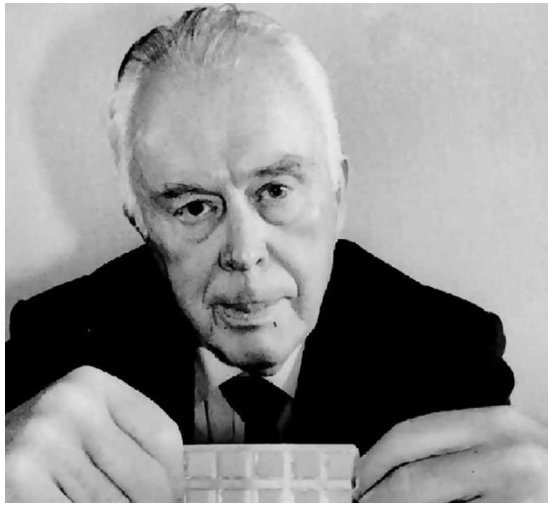
History of Smoking Cessation Part 3



Addiction, pathways to quit, doubt and hope: 1980s-1990s

Development of nicotine gum



While studying the effects of atmospheric pressure on human physiology in submarines, Swedish researchers from the University of Lund, observed that the crew members, under strict smoking bans, used snus, an oral tobacco product. The researchers suggested to the pharmaceutical company, AB Leo, that pure nicotine could be used to aid in smoking cessation. The letter appeared on the desk of Dr. Ove Fernö, the director of research, who himself was a heavy smoker. He immediately saw the potential of using a “clean nicotine” administration form as a means to aid quitting smoking.

The first nicotine chewing gum was produced at AB Leo. The innovation uses an ion-exchange resin, to control the release of nicotine during chewing. The same year Håkan Westling, Professor of Clinical Physiology at Lund University starts the first clinical trials of the gum as an aid to smoking cessation. Nicorette was registered as a drug in Switzerland in 1978, in Canada in 1979, in the UK in 1980, and in Sweden in 1981.

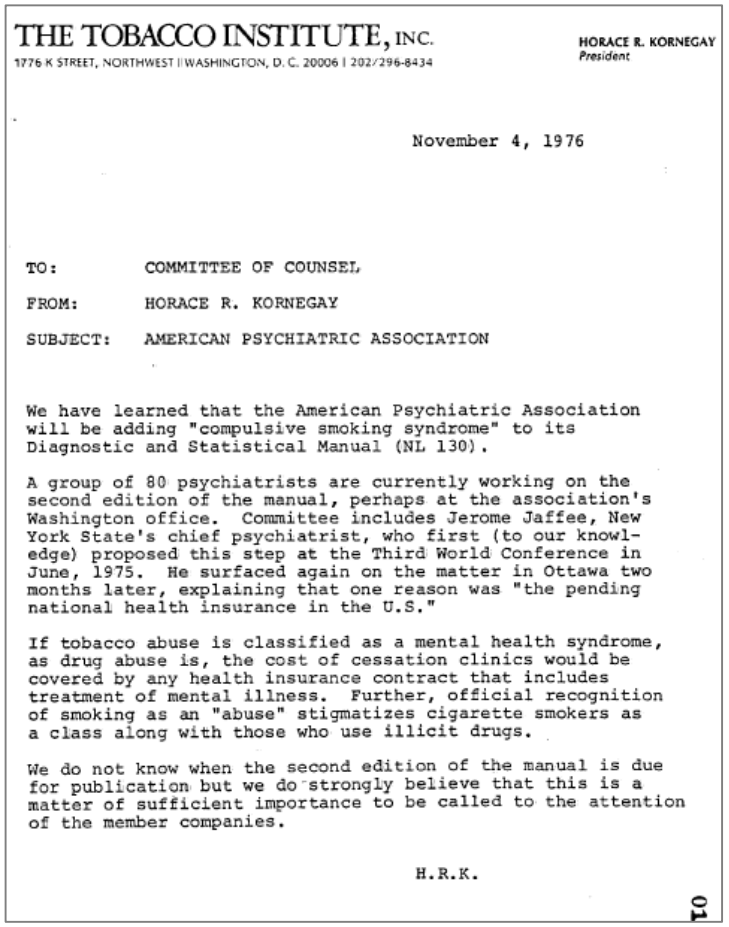
In 1984, after a 34-month review by the US Food and Drug Administration, Nicorette chewing gum was approved and was brought to the US market by Merrell Dow under license from AB Leo. It became a top selling prescription medication in the US for a period of time.

1984 Philip Morris tries to limit Dow's marketing of the nicotine gum

In the 1980s, Philip Morris which purchased chemicals from Dow Chemical for the manufacturing of cigarettes repeatedly threatened to stop doing business with Dow unless they toned down their marketing of nicotine gum which Phillip Morris said they found to be offensive.

Tobacco industry undermines efforts to classify smoking addiction as a mental health disorder

The Tobacco Institute worked industry channels to discourage the American Psychiatry Association from classifying smoking as an addiction, fearing the cost of cessation would be covered in the same way that drug abuse is treated. In a follow-up memo, TI Chair, Horace Kornegay informs them that executives from RJ Reynolds and other companies had [illegible] to pressure the APA to discourage the change in status.



THE TOBACCO INSTITUTE, INC.
1776 K STREET, NORTHWEST | WASHINGTON, D.C. 20006 | 202/296-8434

HORACE R. KORNEGAY
President

November 4, 1976

TO: COMMITTEE OF COUNSEL

FROM: HORACE R. KORNEGAY

SUBJECT: AMERICAN PSYCHIATRIC ASSOCIATION

We have learned that the American Psychiatric Association will be adding "compulsive smoking syndrome" to its Diagnostic and Statistical Manual (NL 130).

A group of 80 psychiatrists are currently working on the second edition of the manual, perhaps at the association's Washington office. Committee includes Jerome Jaffee, New York State's chief psychiatrist, who first (to our knowledge) proposed this step at the Third World Conference in June, 1975. He surfaced again on the matter in Ottawa two months later, explaining that one reason was "the pending national health insurance in the U.S."

If tobacco abuse is classified as a mental health syndrome, as drug abuse is, the cost of cessation clinics would be covered by any health insurance contract that includes treatment of mental illness. Further, official recognition of smoking as an "abuse" stigmatizes cigarette smokers as a class along with those who use illicit drugs.

We do not know when the second edition of the manual is due for publication but we do strongly believe that this is a matter of sufficient importance to be called to the attention of the member companies.

H.R.K.

01

and Statistical Manual, I am pleased to advise that Dr. Richard Proctor, chairman of the Department of Psychiatry at Bowman Gray Medical School, has agreed to write a substantial number of his colleagues to object to this undertaking. This matter was called to Dr. Proctor's attention by Colin Stokes of RJR and after talking with Mr. Stokes, Dr. Proctor is in full agreement that such a classification should not be included in the Diagnostic and Statistical Manual of the APA.

Hopefully, the officers and directors of other companies are taking a similar interest to discourage this move by the APA.

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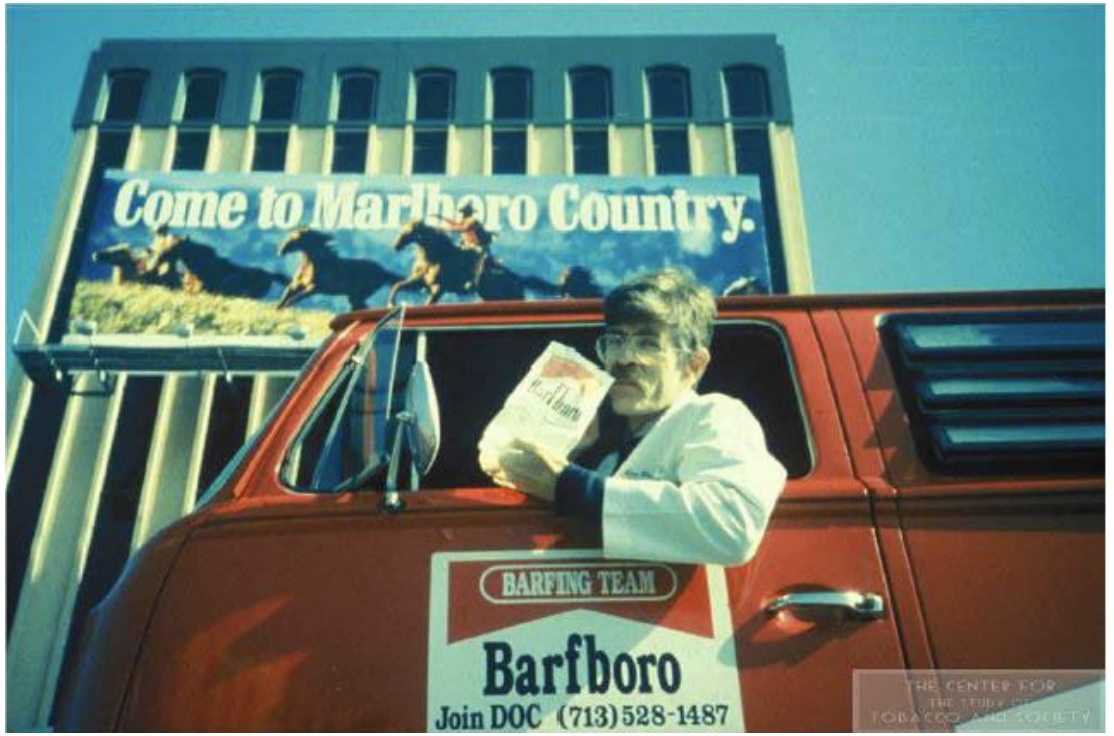
1977 Doctors Ought to Care

Dr. Alan Blum creates Doctors Ought to Care (DOC), the first physicians' group devoted entirely to health promotion. Dr. Blum recruited residents and medical students through the American Academy of Family Physicians and launched DOC chapters in over 100 medical schools and family medicine residency programs.



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1982 Nicotine Anonymous

In 1982, Nicotine Anonymous started in the Southern California living room of co-founder, Rodger F.

The group consisted mostly of Alcoholics Anonymous members who realized their need to focus on their nicotine addiction and to stop smoking. With permission from Alcoholics Anonymous, Nicotine Anonymous adapted the Twelve Steps practice.

Face-to-face meetings have been supplemented by online and telephone sessions.

Clonidine

In the early 1990s, Clonidine was being used as an anti-hypertensive medication but was also suggested that it might be helpful for smokers trying to quit by lessening withdrawal symptoms.

December 1, 1989

Randomized, Controlled Trial of Clonidine for Smoking Cessation in a Primary Care Setting

Peter Franks, MD; Jeffrey Harp, MD; Beth Bell, MD

» Author Affiliations

JAMA. 1989;262(21):3011-3013. doi:10.1001/jama.1989.03430210053029

Results of clinical trials testing Clonidine as a stop smoking treatment were equivocal, even though post-hoc analyses suggested that there may be a small subgroup of smokers who would benefit from using Clonidine.

Given concerns about possible adverse side-effects with Clonidine, it never became a widely used stop smoking treatment.

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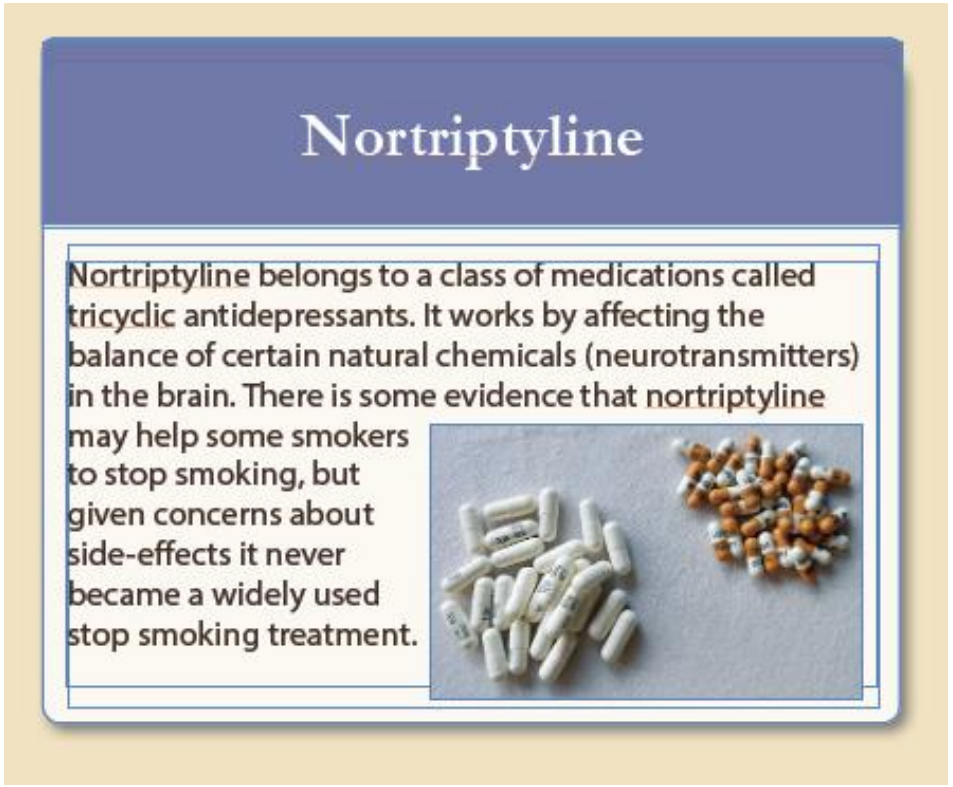
Nortriptyline

“Nortriptyline belongs to a class of medications called tricyclic antidepressants. It works by affecting the balance of certain natural chemicals (neurotransmitters) in the brain. There is some evidence that nortriptyline may help some smokers to stop smoking, but given concerns about side-effects it never became a widely used stop smoking treatment.”



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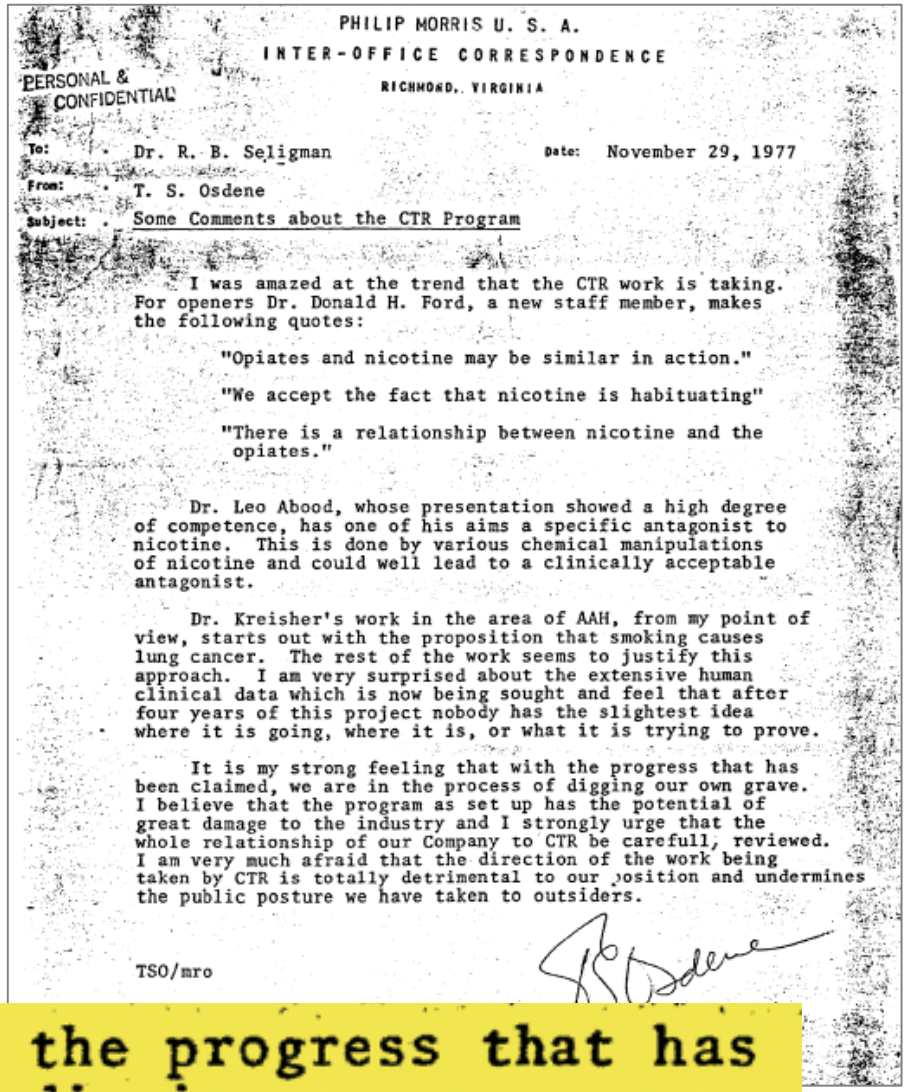
1977 Digging Our Own Grave

Philip Morris' research chief showed concern about Council for Tobacco Research supported scientists, including Dr. Leo Abood, whose work included the development of an antagonist to nicotine that could possibly block the impact of nicotine on the brain.

"It is my strong feeling that with the progress that has been claimed, we are in the process of digging our own grave."



PHILIP MORRIS U. S. A.
INTER-OFFICE CORRESPONDENCE
RICHMOND, VIRGINIA

PERSONAL & CONFIDENTIAL

To: Dr. R. B. Seligman
Date: November 29, 1977
From: T. S. Osdene
Subject: Some Comments about the CTR Program

I was amazed at the trend that the CTR work is taking. For openers Dr. Donald H. Ford, a new staff member, makes the following quotes:

"Opiates and nicotine may be similar in action."

"We accept the fact that nicotine is habituating"

"There is a relationship between nicotine and the opiates."

Dr. Leo Abood, whose presentation showed a high degree of competence, has one of his aims a specific antagonist to nicotine. This is done by various chemical manipulations of nicotine and could well lead to a clinically acceptable antagonist.

Dr. Kreisher's work in the area of AAH, from my point of view, starts out with the proposition that smoking causes lung cancer. The rest of the work seems to justify this approach. I am very surprised about the extensive human clinical data which is now being sought and feel that after four years of this project nobody has the slightest idea where it is going, where it is, or what it is trying to prove.

It is my strong feeling that with the progress that has been claimed, we are in the process of digging our own grave. I believe that the program as set up has the potential of great damage to the industry and I strongly urge that the whole relationship of our Company to CTR be carefull, reviewed. I am very much afraid that the direction of the work being taken by CTR is totally detrimental to our position and undermines the public posture we have taken to outsiders.

TSO/mro

It is my strong feeling that with the progress that has been claimed, we are in the process of digging our own grave.

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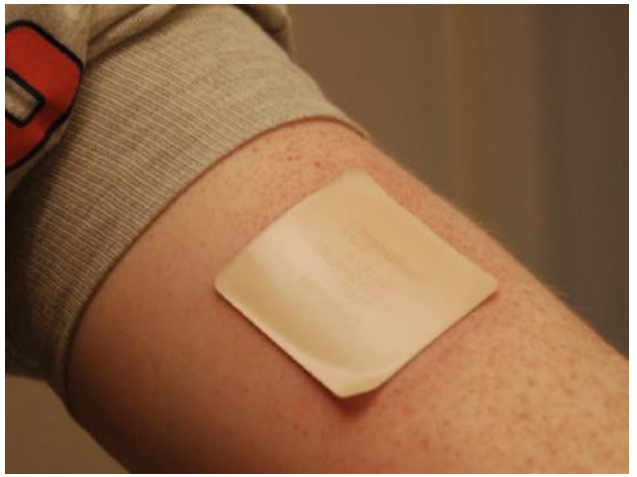
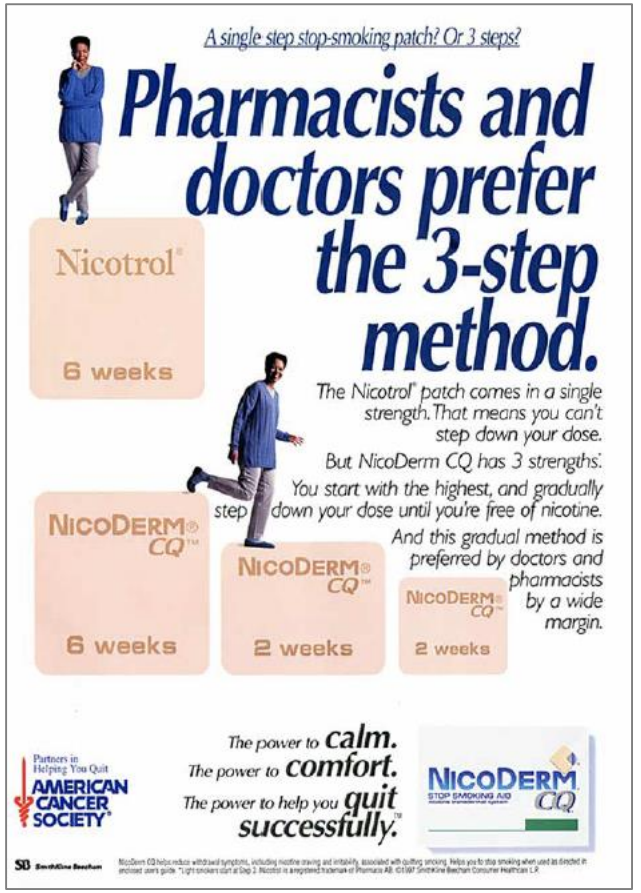
1984 Nicotine patch Invented

The nicotine patch was first invented by doctors in 1984 at UCLA when they discovered that a transdermal nicotine patch could help people quit smoking.

The first study of the transdermal nicotine patch in humans was published in 1984 by Jed Rose, Murray Jarvik, and Daniel Rose, and a publication by Rose et al. in 1985. Frank Etscorn also issued a patent in 1986. Ultimately, the U.S. Patent Office declared a priority decision in favor of Rose et al.

The nicotine patch was approved and marketed in the United States in 1992.





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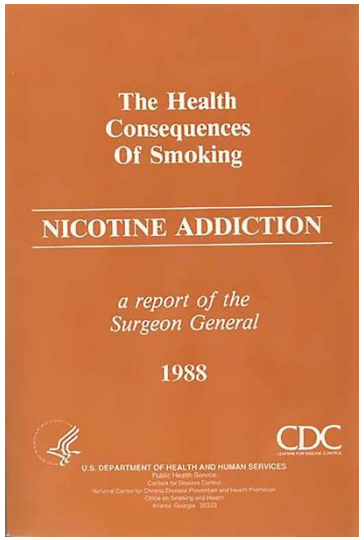
1988 The reason for continued smoking is redefined



The Report of the Surgeon General

"The Health Consequences of Smoking: Nicotine Addiction," C. Everett Koop, examines the scientific evidence that cigarettes and other forms of tobacco are addicting.

Koop would add that in his mind, smoking is "just as addictive as heroin and cocaine."

1985 Quitlines

In 1985, Quit Victoria and later UK Quit in 1988, were the first telephone based programs dedicated to helping smokers quit. In 1992, the California Department of Health Services established the first publicly funded quitline in the US, the California Smokers' Helpline. Quitlines are now available to smokers throughout the world. Quitlines offer tobacco users services, including counseling, information, referrals to cessation resources, self-help materials, web, and mobile phone information and services, information regarding cessation medications, and, in some cases, free or discounted cessation medications. In November 2004 the National Cancer Institute established 1-800-QUIT-NOW as a nation-wide number that links callers to state quitlines.

1992 Mayo Clinic Opens a Residential Treatment Program

The Mayo Clinic's eight-day residential treatment program at the Nicotine Dependence Center in Minnesota still provides an intensive treatment program for stopping smoking with More than 1,300 people treated since the program began in 1992.

MAYO CLINIC

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1993 FDA Bans Many Over the Counter Stop Smoking Aids

The 1993 FDA product ban affected more than two dozen smoking deterrents sold over the counter as pills, tablets, lozenges and chewing gum under names like Cigarrest, Bantron, Tabmint and Nikoban, and others.

Edgefield's Tabmint Silver Acetate, smoking deterrent chewing gum, reacts with cigarette smoke, giving the smoke a strong metallic taste.

Products containing Lobelia Sulfate were also banned.

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1994 The Society for Research on Nicotine and Tobacco

SRNT was initially created by scientists who participated in the Third Nicotine Roundtable of the American Society of Addiction Medicine in 1993 and sought to focus on nicotine and tobacco use. The mission of SRNT is to “stimulate the generation and dissemination of new knowledge concerning nicotine in all its manifestations - from molecular to societal.” In 1999, SRNT published the first volume of the scientific journal, Nicotine and Tobacco *Research.*

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Industry “Off Ramp” Influence entry and exit rates…

“ We cannot ever be comfortable selling a product that most of our customers would stop using if they could.”

With sufficient knowledge/information, we should be able to maintain/increase the size of the total market by influencing entry/exit rates; and we should be able to improve our share of the market by targeting our products to the crucial entry/exit groups at both ends of that total market. That assumes that the entry/exit gates will remain substantially as they are now.

However, we cannot ever be comfortable selling a product which most of our customers would stop using if they could. That is to say, if the exit gate from our market should suddenly open, we could be out of business almost overnight.

- Some slow but steady "progress" is being made in developing techniques for stopping smoking; but no universal, easy method is yet in sight.

- The probability of such a method appearing in the near term is small.

- The probability of such a method appearing over the long term approaches 100%.

- If/when that occurs, our options include:

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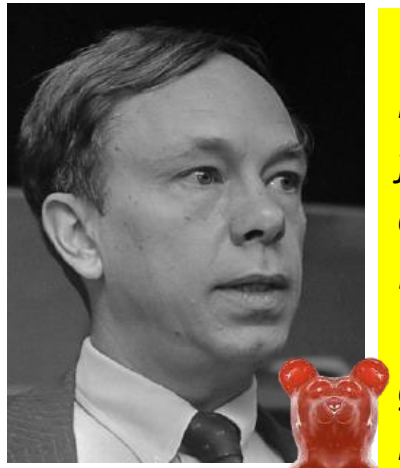
Tobacco Industry Addiction Denials and Gummy Bears

The Tobacco Industry launched a campaign denying the validity of the 1988 Report of the Surgeon Generals on smoking and addiction with advertising, news commentaries, and editorials. They would also carry the denial into the courtroom.

Gummy Bears: Asked if he thought that cigarettes were addictive, James J. Morgan, president of Philip Morris, stated in 1997 sworn testimony:



"...If they [cigarettes] are behaviorally addictive or habit-forming, they are much more like caffeine, or in my case, Gummy Bears. I love gummy bears...and I want gummy bears, and I like gummy bears, and I eat gummy bears, and I don't like it when I don't eat my gummy bears, but I'm certainly not addicted to them."

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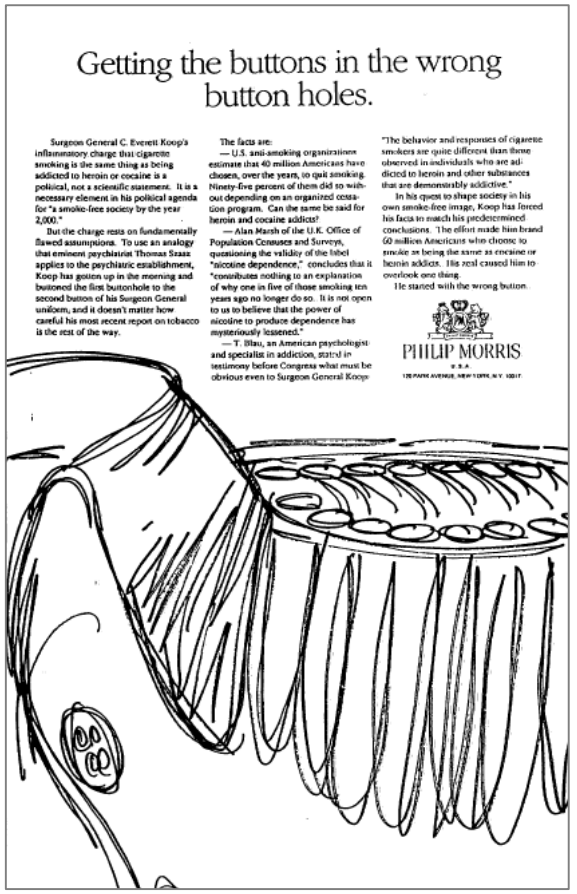
Tobacco Institute media spokespeople, Walker Merryman, Brennan Dawson (Moran) and others appeared on news shows and interviews to dispute the 1988 report on smoking and addiction on behalf of the tobacco industry.


Getting the buttons in the wrong button holes.

Surgeon General C. Everett Koop's inflammatory charge that cigarette smoking is the same thing as being addicted to heroin or cocaine is a political, not a scientific statement. It is a necessary element in his political agenda for "a smoke-free society by the year 2,000."

But the charge rests on fundamentally flawed assumptions. To use an analogy that eminent psychiatrist Thomas Szasz applies to the psychiatric establishment, Koop has gotten up in the morning and buttoned the first buttonhole to the second button of his Surgeon General uniform, and it doesn't matter how careful his most recent report on tobacco is the rest of the way.

The facts are:

— U.S. anti-smoking organizations estimate that 40 million Americans have chosen, over the years, to quit smoking. Ninety-five percent of them did so without depending on an organized cessation program. Can the same be said for heroin and cocaine addicts?

— Alan Marsh of the U.K. Office of Population Censuses and Surveys, questioning the validity of the label "nicotine dependence," concludes that it "contributes nothing to an explanation of why one in five of those smoking ten years ago no longer do so. It is not open to us to believe that the power of nicotine to produce dependence has mysteriously lessened."

— T. Blau, an American psychologist and specialist in addiction, stated in testimony before Congress what must be obvious even to Surgeon General Koop:

"The behavior and responses of cigarette smokers are quite different than those observed in individuals who are addicted to heroin and other substances that are demonstrably addictive."

In his quest to shape society in his own smoke-free image, Koop has forced his facts to match his predetermined conclusions. The effort made him brand 60 million Americans who choose to smoke as being the same as cocaine or heroin addicts. His zeal caused him to overlook one thing.

He started with the wrong button.

PHILIP MORRIS

1988 Tobacco Institute press release

1994 Tobacco Executives Testify Before Congress

The New York Times

NEW YORK, FRIDAY, APRIL 15, 1994

Tobacco Chiefs Say Cigarettes Aren't Addictive

Stephen Crowley/The New York Times

Top executives from seven tobacco companies, at a hearing on smoking. They are identified on page A20.

1996 The Nicotine Inhaler and Nicotine Nasal Spray

The nicotine inhaler cartridge contains nicotine. The user inhales the nicotine vapor, which is absorbed into the mouth and throat area.

Nicotine nasal spray stemmed from work showing the rapid rate of nicotine absorption into the body from nasal snuff. Both forms of nicotine replacement therapy can provide faster-acting nicotine relief from cigarette withdrawal. Both are prescription medications.

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1996 FDA approves NRT medications for over the counter purchase

In 1996 The FDA approved the nicotine patch, gum, and later the nicotine lozenge for over the counter purchase.

The Nicotine inhaler and nasal spray remain prescription medications.

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Nortriptyline

Nortriptyline belongs to a class of medications called tricyclic antidepressants. It works by affecting the balance of certain natural chemicals (neurotransmitters) in the brain.

There is some evidence that nortriptyline may help some smokers to stop smoking, but given concerns about side-effects it never became a widely used stop smoking treatment.

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1997 Bupropion Hydrochloride

In 1974, Nariman Mehta of Burroughs Wellcome (now GlaxoSmithKline) invented Bupropion Hydrochloride. Approved by the United States Food and Drug Administration as an antidepressant, people taking Wellbutrin for depression reported losing their desire to smoke. In 1997, as Zyban, it was approved for use as a smoking cessation medication.

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