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# Nicotine Maintenance and its Role in Comprehensive Tobacco Control Programs

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An Analysis of Harm Reduction Strategies, Implications and Recommendations





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## DEDICATION

*This paper is dedicated to Jon Lloyd  
whose gift with words gave voice to a  
vision and inspired us to succeed.*

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## Executive Summary

The California Tobacco Control Program (CTCP) believes that harm reduction as a tobacco control strategy poses a serious threat to public health efforts aimed at reducing the toll of death and disease caused by tobacco use. The tobacco industry is already using the harm reduction concept in its marketing of existing products, and all signs point to both the tobacco industry and the pharmaceutical industry devoting considerable research and development resources to new products that will fit within the harm reduction paradigm.

Therefore, it is imperative that public health officials take a critical look at this emerging strategy. To that end, this paper has three goals:

- To assess harm reduction (or, more accurately, nicotine maintenance) as a public health strategy
- To define criteria that must be met prior to the endorsement of this strategy by public health agencies
- To recommend specific federal regulations for governing the products and messages comprising this strategy

The concept of tobacco harm reduction is tied to the availability of an array of nicotine-containing products that may be less hazardous to the user than conventional combustible cigarettes. Because these nicotine products are intended for long-term use, the CTCP has concluded that the harm reduction strategy is actually a nicotine maintenance strategy. Nicotine maintenance is the strategy to provide tobacco users concerned about their health with a new option to substitute, in place of conventional combustible cigarettes, the long-term use of another, potentially less dangerous nicotine-delivery product that can still satisfy the user's nicotine addiction.

Nicotine maintenance is a two-pronged strategy: it requires products and promotion. The primary concern about the products focuses on their health risks to users; the concern about the promotion of these products focuses on the impact such marketing may have on the population at large.

Nicotine maintenance products are known as PREPs: potentially reduced exposure products. At the present time, PREPs fall into three categories:

- Modified cigarettes and cigarette-like products
- Smokeless tobacco, snus, and tobacco lozenges
- Medicinal nicotine currently under development by pharmaceutical companies that is intended for long-term use rather than as an aid to cessation

“Nicotine maintenance is a two-pronged strategy: it requires products and promotion. The primary concern about the products focuses on their health risks to users; the concern about the promotion of these products focuses on the impact such marketing may have on the population at large”

“The CTCP is concerned that unfettered promotion of nicotine maintenance products by tobacco and pharmaceutical companies has the potential to foster the norm that addiction to nicotine is acceptable, and is of little health consequence to the user or the population as a whole”

Various sources have touted each of these products as the next safest alternative to quitting because they reduce exposure to one or more tobacco toxicants. The three types of PREPs clearly present a continuum of health risk to the user, with combustible products likely posing a greater risk to an individual's health than medicinal nicotine products.

The greatest danger of the nicotine maintenance strategy lies in the marketing of these products. The CTCP is concerned that unfettered promotion of nicotine maintenance products by tobacco and pharmaceutical companies has the potential to foster the norm that addiction to nicotine is acceptable, and is of little health consequence to the user or the population as a whole. Such marketing would undermine and damage the ability of states and local governments to implement or sustain proven strategies such as tobacco taxes, secondhand smoke restrictions, counter-advertising media campaigns, and cessation quitlines. While this paper lays out the CTCP's position regarding nicotine maintenance, we want to make it clear that we do not take issue with the potential public health value or use of nicotine replacement therapy or other Food and Drug Administration (FDA)-approved pharmaceutical products that are promoted and used to aid tobacco cessation. The CTCP's concern lies with the proposed promotion and use of medicinal nicotine as a long-term strategy in lieu of quitting.

The CTCP believes that tobacco cessation and nicotine maintenance are contradictory strategies. Promoting the co-existence of tobacco cessation and nicotine maintenance strategies ignores the complexity of how product marketing is received and acted upon by tobacco users and potential users, as well as policy makers who are in a position to allocate resources and enact policies that regulate smoking and the sale and promotion of tobacco products.

Whether nicotine maintenance messages are conveyed by the public health community, tobacco companies or the pharmaceutical industry, they will likely legitimize nicotine addiction. In doing so, these messages will decrease motivation for quitting, decrease quit attempts, slow tobacco cessation, increase the rate of youth initiation, and undermine the effectiveness of comprehensive tobacco control programs that seek to denormalize tobacco use and promote cessation. Of concern is that some in the public health community have already recommended the promotion of smokeless tobacco, snus, and long-term use of NRT (Bates C, Fagerström K, Jarvis MJ, Kunze M, McNeill A, Ramström, 2003; Sweanor D, 2003; Kozlowski LT, O'Connor RJ, Quinio Edwards B, 2003).

The tobacco industry is quite aware of smokers' increasing concern about the health effects of smoking, as well as the public's increasing intolerance of secondhand smoke. Lawsuits and the accompanying financial instability have shaken the tobacco industry. Settlements have led to price hikes and reduced consumption. Faced with the prospect of a steady decrease in cigarette sales, the

tobacco industry is looking for a “turn around” strategy. To protect itself from future lawsuits and further hostile legislation, it must establish a respectable public image, demonstrate repentance by acknowledging the health effects of tobacco use, and seek legitimacy for new products positioned as reducing health risks while creating a safe harbor through FDA oversight of these products. These products are not aimed at the highly addicted, hard core smoker—but rather the smoker who is contemplating quitting and youth and young adults who are not yet established tobacco users. Ads for these products make claims such as “all the taste...less of the toxins” (Brown & Williamson’s Advance cigarettes); “reduced carcinogens, premium taste” (Vector’s Omni cigarettes); and “may present less risk of cancer, chronic bronchitis and possibly emphysema” (R.J. Reynolds’s Eclipse).

The CTCP is concerned that as nicotine maintenance products are produced and marketed, they may not be used in the way intended, and that messages about these products may be perceived and acted upon in ways not anticipated. Given the lessons learned from the history of “light” cigarettes, the CTCP has defined criteria it believes must be met before the public health community endorses nicotine maintenance as a viable public health strategy.

The CTCP recognizes that nicotine maintenance is already a reality in the marketplace, and its influence will only increase. It is likely that new nicotine maintenance products will be brought to market prior to the existence of sufficient information to assess their public health impact as outlined by the CTCP’s criteria. Therefore, we also provide specific recommendations for federal regulation of tobacco and nicotine products that we believe will prevent or ameliorate possible unintended consequences of nicotine maintenance and will help the nation maintain its steady progress toward reducing and eventually eliminating tobacco-related morbidity and mortality.

“The CTCP is concerned that as nicotine maintenance products are produced and marketed, they may not be used in the way intended, and that messages about these products may be perceived and acted upon in ways not anticipated”



## Introduction: “Harm reduction” commands our attention

**W**ho could object to the concept of harm reduction? It sounds simple. It equates an obviously desirable goal – that of reducing harm from smoking – with the unproven, potentially harmful effects of long term use of alternative nicotine delivery devices. It arbitrarily banishes from consideration the public health strategies that have been shown to be effective, such as restricting smoking in public places and increasing excise taxes. It limits consideration to novel and unproven technologies.

For quite some time, the California Tobacco Control Program (CTCP) has been alarmed at how quickly harm reduction, the substitution of possibly less harmful products for conventional combustible cigarettes, has been gaining legitimacy in the public health community. As a leader in the tobacco control arena, the CTCP felt compelled to conduct an in-depth analysis of the possible impact of harm reduction, and in 2004 developed the first draft of this position paper, *Nicotine Maintenance and Tobacco Control*.

On September 8 and 9, 2004, the CTCP invited representatives from public health, academia, government, advocacy groups, public relations and other relevant fields to gather in Sacramento, California for the *Seduction of Harm Reduction Summit*. The purpose of this invitation-only summit was to elicit reaction to the draft position paper, articulate the CTCP’s views on harm reduction, and listen to a range of experts from diverse fields discuss various aspects of the harm reduction strategy. The Summit’s format allowed for an extensive exchange of ideas and opinions among CTCP representatives, presenters and attendees. Additionally, the CTCP received a considerable body of written comments on the draft paper from Summit participants and from invited experts who were unable to attend the Summit.

Proceedings of the *Seduction of Harm Reduction Summit*, which reflect the presentations, participant commentary and written correspondence, are available on request from the CTCP. It is important to note that participation in the Summit and/or written submission of written commentary does not in any way imply endorsement of the CTCP’s position. The critical analysis and review provided by Summit participants, a Harm Reduction Task Force convened by the CTCP, and others helped the CTCP revise its recommendation and crystallize its arguments for this paper. (See Appendix A for members of the Harm Reduction Task Force.)

In this paper, we explain the CTCP’s concerns about harm reduction and its possible endorsement by public health agencies. We also offer recommendations for regulating the manufacture, promotion, and distribution of so-called “reduced harm” products.

## Tobacco Control: Still a public health imperative

The need for vigorous and effective tobacco control continues to be an urgent public health priority. The 1998 Master Settlement Agreement (MSA)<sup>1</sup> did not end the blight of tobacco-related disease and death; in fact, it gave rise to new and different challenges in terms of tobacco industry promotion, as well as stimulated political support for progressive regulatory and legislative controls on tobacco use.

Forty years after the publication of the Surgeon General's 1964 *Report on Smoking and Health*, the extent of tobacco-related morbidity and mortality remains staggering: 46 million Americans still smoke (CDC 2004). The societal costs of tobacco-related death and disease approach \$100 billion each year (USDHHS 2000). Nonsmokers continue to suffer, as well. An estimated 3,000 lung cancer deaths and 35,000 coronary heart disease deaths occur annually among adult nonsmokers in the U.S. as a result of exposure to secondhand smoke (CDC 2002), and an estimated 8,000 to 26,000 new asthma cases in children are associated with secondhand smoke exposure each year (EPA 1997).

Even so, the public health community has made great strides against the scourge of tobacco, especially in states such as California where adequately funded comprehensive tobacco control programs are operating. Strategies that have proven successful in these programs include an array of activities at the state and local level to change the social norm surrounding tobacco use, including tobacco free workplace laws, tobacco tax increases, and countering pro-tobacco advertising and product access.

In recent years, the public health strategy known as harm reduction has entered the tobacco control vernacular. Harm reduction in a public health context did not originate in tobacco control; other public health programs have adopted or experimented with ideas of harm reduction, such as needle exchange programs to help stop the spread of HIV among intravenous drug users (IOM 2001). Some of these other public health harm reduction programs have been controversial, and the assessment of their impact is ongoing.

As the drumbeat grows louder for incorporating harm reduction into publicly funded tobacco control programs<sup>2</sup>, the CTCP believes the time has come to take a

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1 The Master Settlement Agreement (MSA) is a legal contract established in 1998 between 46 states, including California, and five U.S. Territories, with participating tobacco manufacturers. The MSA provides numerous restrictions and prohibitions, including bans on the use of cartoons in tobacco advertisements, youth exposure to sampling, certain sponsorships, and the use of most outdoor advertisements. (Source: Office of the Attorney General of the State of California website, <http://ag.ca.gov/tobacco/faq.htm>)

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2 Appendix B lists a number of publications discussing harm control as a possible public health strategy.

critical look at this unproven strategy within the context of decreasing tobacco use. The goals of this paper are as follows:

- To assess harm reduction (or, more accurately, nicotine maintenance) as a public health strategy,
- To define criteria that must be met prior to the endorsement of this strategy by public health agencies, and
- To recommend specific federal regulations for governing the products and messages comprising this strategy.

### **Not just semantics: Harm reduction is nicotine maintenance**

Proponents of the harm reduction strategy characterize it as decreasing the burden of death and disease “without completely eliminating tobacco and nicotine use” (IOM 2001). The concept revolves around the availability of an array of nicotine-containing products that may be less hazardous to the user than conventional combustible cigarettes.

Because these nicotine products are intended for long-term use, the CTCP concludes that the harm reduction strategy is actually a nicotine maintenance strategy. Therefore, in the interest of accuracy, this paper refers to harm reduction as nicotine maintenance. Nicotine maintenance, then, is a strategy to provide tobacco users concerned about their health with a new, perhaps more-easily achievable option as opposed to reducing their current tobacco use or quitting. The new option is to substitute, in place of conventional combustible cigarettes, the long-term use of another, potentially less dangerous nicotine-delivery product that can still satisfy the user’s nicotine addiction.

### **A two-part strategy: Nicotine maintenance encompasses products and product promotion**

**N**icotine maintenance as a tobacco control strategy rests equally on two pillars: products and promotion. The concern about the products focuses primarily on the health risks they pose to users; the concern about the promotion of these products focuses on the impact such marketing may have on the population at large.

“Nicotine maintenance, then, is a strategy to provide tobacco users concerned about their health with a new, perhaps more-easily achievable option as opposed to reducing their current tobacco use or quitting. The new option is to substitute, in place of conventional combustible cigarettes, the long-term use of another, potentially less dangerous nicotine-delivery product that can still satisfy the user’s nicotine addiction”

## **PREPs: Supplying the nicotine in nicotine maintenance**

The nicotine maintenance strategy centers on the availability of nicotine-containing products claiming to be less hazardous than conventional combustible cigarettes. These products are known as PREPs: potentially reduced exposure products. At the present time, PREPs fall into three categories:

- Modified cigarettes and cigarette-like products
- Smokeless tobacco, snus, and tobacco lozenges
- Medicinal nicotine currently under development by pharmaceutical companies (perhaps in the form of gum, patches, and inhalants) that will be designed and marketed for long-term use rather than as an aid to cessation

Each of these types of products has been positioned by various sources as a product that conventional combustible cigarette users should switch to as the next safest alternative to quitting because it reduces exposure to one or more carcinogens or chemicals associated with cardiovascular or respiratory disease. The three types of PREPs clearly present a continuum of health risk to the user. While it is difficult to quantify the different and specific risks, they can be ranked relative to one another, with combustible products posing a greater risk to an individual's health than medicinal nicotine products.

Modified cigarettes may reduce exposure to one or more toxicants, but they still burn or heat tobacco, and will most likely produce carbon monoxide and possible carcinogens. Most public health researchers believe that these kinds of combustible products are unlikely to reduce health risks sufficiently to provide large benefits (Giovino, JAMA, 2004).

Smokeless tobacco as currently marketed in the U.S. contains carcinogens such as benzo-a-pyrene, NNK, NNN, formaldehyde, acetaldehyde, and cadmium. Although it has fewer carcinogens and none of the respiratory illnesses associated with cigarettes, smokeless tobacco does pose health risks to users. Smokeless tobacco causes oral-cavity cancer and may cause pancreatic cancer (IARC 2005).

Snus is a smokeless tobacco product marketed in Sweden that has fewer nitrosamines than the smokeless tobacco products marketed in the U.S. However, products such as snus "still contain unacceptably high levels of potent carcinogens" (Hecht 2003). Furthermore, there is considerable scientific debate around a reduction in lung cancer cases in men in Sweden and the attribution of this decline to snus. The current evidence is ecological and is based on a single country. Presenting snus as an alternative to smoking would appear to be a male-specific strategy, and may lead to concurrent snus use and smoking, rather than substituting snus for smoking.

Long-term medical nicotine may pose small risks to the individual user. According to leading researchers the risks include the fact that nicotine is an angiogenic agent (Hecht 2003), may be a tumor promoter, and acutely impacts the cardiovascular system by increasing blood pressure and heart rate (Benowitz 1998).

**The CTCP’s position, as it relates to medicinal nicotine products, does not take issue with the potential public health value or use of nicotine replacement therapy or other FDA-approved pharmaceutical products that are promoted and used to aid tobacco cessation. The CTCP’s concern lies with the proposed use of medicinal nicotine as a long-term strategy in lieu of quitting.**

### **The menace of marketing: Nicotine maintenance promotion threatens public health**

The mere existence of PREPs does not necessarily increase the danger to public health; rather, it is the promotion of these PREPs that threatens the public’s health. The CTCP is concerned about nicotine maintenance promotion emanating from two different sources: First, the tobacco and pharmaceutical giants who are or will be seeking to reinforce the buying habits of their current customers and recruiting new consumers, and second, public health agencies that may endorse and then decide to introduce nicotine maintenance messages into their mix of tobacco control media campaigns and programming.

#### **The bottom line: Nicotine maintenance is profitable**

There are approximately 4 million adult smokers in California (CDHS/TCS, Tobacco Control Update, 2004) and 46 million smokers nationwide (CDC 2002). Smokers represent a huge market for tobacco and pharmaceutical companies, and these industries have billion dollar marketing budgets at their disposal to promote their products. At the same time that tobacco companies are seeking to grow their market share with modified cigarettes and other tobacco products, the pharmaceutical industry may be promoting medicinal nicotine maintenance products as another option to smokers who might otherwise have quit. The public health community must always keep in mind that, at the end of the day, a primary interest of tobacco and pharmaceutical companies is to bring in revenue and increase shareholder value. The goal of all commercial advertising for PREPs, regardless of the type, is to create a desire for the product. This advertising must:

- convince consumers that they can receive the same enjoyment and satisfaction without the risk,
- convince tobacco users they do not have to quit, and
- convince non-users that the “pleasure” outweighs the risks so they

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“An endorsement by the public health establishment of “reduced harm” products may well give the impression of a new partnership or alignment of views between public health and the tobacco industry”

should try the product.

All evidence points to the fact that the tobacco industry is already laying the groundwork for a “harm reduction” marketing assault on smokers who are concerned about their health and are considering quitting. Since the MSA, tobacco companies have begun acknowledging the damaging effects of smoking. For example, Philip Morris USA says on its website:

“Philip Morris USA (PM USA) agrees with the overwhelming medical and scientific consensus that cigarette smoking causes lung cancer, heart disease, emphysema and other serious diseases in smokers. Smokers are far more likely to develop serious diseases, like lung cancer, than nonsmokers. There is no safe cigarette.” ([www.philipmorrisusa.com/en/health\\_issues/cigarette\\_smoking\\_and\\_disease.asp](http://www.philipmorrisusa.com/en/health_issues/cigarette_smoking_and_disease.asp), accessed March 10, 2005)

In another area of the website, Philip Morris states:

“We also believe that the public should be guided by the conclusions of public health officials regarding the health effects of secondhand smoke in deciding whether to be in places where secondhand smoke is present, or if they are smokers, when and where to smoke around others. We also believe that the conclusions of public health officials concerning environmental tobacco smoke are sufficient to warrant certain measures that regulate smoking.” ([www.philipmorrisusa.com/en/policies\\_practices/smoking\\_restrictions.asp](http://www.philipmorrisusa.com/en/policies_practices/smoking_restrictions.asp), accessed March 10, 2005)

It appears that Philip Morris is now positioning itself to be the solution to tobacco-related disease and death. It is an interesting change of tone from earlier days; “medical and scientific consensus” is suddenly valid, and “public health officials” are now characterized as guardians of the public’s health, rather than bureaucrats working to take away personal choice. An endorsement by the public health establishment of “reduced harm” products may well give the impression of a new partnership or alignment of views between public health and the tobacco industry.

The United States Smokeless Tobacco Co. (USST) is clearly attempting to leverage the nicotine maintenance concept. USST’s current (2005) advertising campaign promotes the idea that smokeless tobacco allows users to maintain their nicotine addiction despite the restrictions imposed by smoke-free indoor air regulations.

One widely circulating magazine advertisement states:

“With all the smoking areas removed from the building, Phil knew his best

option was to head straight for the solution. Enjoy tobacco the smoke-free way with Copenhagen® or Skoal®... Maybe it's time to find your solution—and leave the smoke behind." (USST, Golf, 2005)

Another widely circulating advertisement seen in many national magazines promotes smokeless tobacco use during smoke-free flights:

"Enjoy tobacco on a 4-hour flight? Absolutely. Enjoy tobacco the smoke-free way with Copenhagen® or Skoal®... Maybe it's time to find your solution—and leave the smoke behind." (USST, Money, 2005)

Each of the current ads features a light gray symbol with white text stating "This product is not a safe alternative to cigarettes," a warning label that USST would apparently like to do without. In 2003, USST requested an advisory opinion of the U.S. Federal Trade Commission (FTC) regarding the acceptability of advertising smokeless tobacco as a significantly reduced risk alternative to conventional combustible cigarettes (Cave 2002). (The letter requesting such an opinion was later withdrawn before it could be addressed by the FTC). USST is not alone in positioning smokeless tobacco as a safer alternative to smoking; even some public health researchers have advocated for just such a strategy (Rodu 1995). The adoption of nicotine maintenance as a public health strategy would most certainly be favored by USST.

### **Messaging is more complex than you may think**

In his presentation at the *Seduction of Harm Reduction Summit*, Dr. Richard Pollay noted that while the tobacco control community often focuses on the role of advertising as a recruitment tool for new smokers, advertising also plays an important role in reassuring and reinforcing existing smokers to continue to smoke (Pollay 2004). It is conceivable that promotion of harm reduction products by either the tobacco or pharmaceutical industries will have a similar effect in terms of reassuring and reinforcing continued tobacco use.

Similarly, at the *Seduction of Harm Reduction Summit*, Dr. Paul Bloom discussed how "remedy" messages are perceived differently by consumers who have the problem that the remedy is trying to ameliorate than those who do not. He recounted that in his own research on such messages, smokers perceived less risk from continuing to smoke following an American Cancer Society ad about nicotine replacement therapy because they perceived a remedy to quit, whereas nonsmokers who saw the message were even less inclined to smoke than before seeing the message (Bloom 2004). Again, it is conceivable that promotion of modified cigarette products or smokeless tobacco as safer alternatives to conventional combustible cigarettes may result in heavier use of these products or increased initiation.

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During her presentation at the Summit, Dr. Dorothy Hatsukami also reflected upon the implications of marketing harm reduction products, noting that the message communicated to the consumer is not necessarily the one received. She stated that the general public misinterprets reduced exposure claims as being equivalent to reduced risk and proposed that tobacco companies should not be allowed to advertise products as reducing exposure to toxicants (Hatsukami 2004). She described a study examining the impact of Eclipse<sup>®</sup>, a modified PREP cigarette, which found that smokers who saw Eclipse’s<sup>®</sup> reduced reduction claims became less interested in quitting. Interest in Eclipse<sup>®</sup> was greatest among smokers who were contemplating quitting (Shiffman 2004).

The CTCP is concerned that unfettered promotion of nicotine maintenance products by the tobacco or pharmaceutical companies has the potential to foster the norm that addiction to nicotine is acceptable in any form. Such marketing would undermine and damage the ability of states and local governments to implement or sustain proven strategies such as tobacco taxes, secondhand smoke restrictions, counter-advertising media campaigns, and cessation quitlines. Additionally, the CTCP is concerned that as nicotine maintenance products are produced and marketed, they may not be used in the way intended, and that messages about these products may be perceived and acted upon in ways not anticipated.

It is difficult to dismiss the potential for nicotine maintenance marketing to undermine comprehensive tobacco control programs whose goals are cessation, freedom from nicotine addiction, and protection from secondhand smoke exposure. Well-funded public health media campaigns to educate consumers about cessation and secondhand smoke pale in comparison to the marketing campaigns that tobacco and pharmaceutical companies have the resources to mount.

**Déjà vu: Lessons learned from the “light cigarette fiasco”**

Why is the CTCP so skeptical about the latest in a long line of “less hazardous” tobacco products? It stems partly from what many in the tobacco control community refer to as the “light cigarette fiasco.”

In the 1950s, animal studies demonstrated the carcinogenic qualities of tar and other toxic substances found in cigarette smoke. The results of these studies convinced much of the health care community that the general public should be warned about the dangers of smoking, and that cigarette manufacturers should be encouraged to modify their products to try to lessen the harmful effects of cigarette smoke.

The tobacco industry responded to this marketing challenge by making largely cosmetic changes, such as placing filters on cigarettes and trumpeting claims of low tar and nicotine yields in their advertising campaigns. The federal government

played a role, as well, by requiring tar and nicotine yields as measured by FTC smoke machines to be placed on cigarette packaging. By remaining largely silent, the American health establishment implicitly endorsed the idea that concerned smokers should turn to “low yield” cigarettes (Fairchild 2004).

In 1968, the National Cancer Institute (NCI) partnered with major U.S. cigarette manufacturers in a government-supported research project to develop a safer cigarette. The “Less Hazardous Cigarette Working Group” (later changed to the more industry-friendly “Tobacco Working Group”) did not succeed in developing a less hazardous cigarette, but its work impacted the health of millions nonetheless. In 1971, Dr. Gio Batta Gori, Deputy Director of the NCI research program, reported that “smokers of filter cigarettes delivering less tar and nicotine show a remarkably decreased risk of disease; these studies give unequivocal proof in man that reduced tar and nicotine provide the first model of a less hazardous cigarette” (Kluger 1997).

The public health community largely accepted the claim that low-tar and nicotine cigarettes were less likely to cause lung cancer. In fact, the 1981 Surgeon General’s report explicitly recommended that smokers switch to low-yield cigarettes as a way to reduce health risks (U.S. Surgeon General 1981). The smoking public took heed; currently about 85% of the cigarettes sold in the U.S. are low-yield cigarettes (FTC, 2005). It was later revealed, however, that the tobacco industry had discovered how to manipulate cigarettes so that the yields shown by the FTC’s smoking machines were considerably lower than those experienced by actual smokers.

Research also began to reveal that smokers adjusted their smoking behavior, consciously or unconsciously, in order to satisfy their nicotine addiction. Some smokers consumed a greater number of cigarettes; others covered up the filter’s holes or inhaled each breath of smoke more deeply. Deceived by sophisticated advertising campaigns, “light” and “ultra light” smokers actually extracted more tar, nicotine, carbon monoxide and other toxicants than they would have if they had never switched (Djordjevic 2000).

Furthermore, smokers who switched to low tar cigarettes were more likely to have considered quitting but were less likely to have quit than those who smoked high-yield brands (Giovino 1996). The public health community can now see that by discouraging smokers from quitting and encouraging uptake of these supposedly safer cigarettes, especially by young people and women, this “illusion of risk reduction” slowed the decline in smoking rates and contributed significantly to the rise in the incidence of tobacco-related disease and death over the last 30 years.

What lessons can the public health community take away from this history? First, no so-called “safer” or “less hazardous” tobacco or nicotine product should be allowed on the market until lengthy controlled clinical trials determine scientifically

“These new tobacco industry products are not aimed at the highly addicted, hard core smoker, but rather the smoker who is contemplating quitting and youth and young adults who are not yet established tobacco users”

that it really is substantially less hazardous to the individual and to the population. Controlled clinical trials conducted over considerable periods of time, coupled with careful surveillance, are needed to reveal unintended consequences such as those that occurred with light cigarettes.

The second lesson from the “light cigarette fiasco” is one the public health community knows well: industries that profit from nicotine addiction have tremendous influence in shaping the research and policy decisions that affect them. Vigilance is required to prevent their undue influence as public health officials and policy makers endeavor to protect the public’s health.

**Nicotine maintenance: big tobacco’s turn around strategy**

The tobacco industry is quite aware of smokers’ increasing concern about the health effects of smoking, as well as the public’s increasing intolerance of secondhand smoke. Lawsuits and the accompanying financial instability have shaken the tobacco industry. Settlements have led to price hikes and reduced consumption. Faced with the prospect of a steady decrease in cigarette sales, the tobacco industry is looking for a “turn around” strategy. The CTCP believes that to protect itself from future lawsuits and further hostile legislation, the tobacco industry must:

- Create a clean and respectable public image
- Demonstrate repentance by acknowledging health effects of tobacco use
- Work with public health groups to demonstrate new respect for public health concerns
- Secure FDA legislation to transfer liability for tobacco products onto the FDA by having the FDA set the standards for reduced risk products
- Secure FDA recognition of PREPs in order to legitimize these products

Harm reduction products represent the turn around strategy, and investors are paying attention. In her presentation at the *Seduction of Harm Reduction Summit*, Dr. Corinne Husten quoted a JPMorgan report which stated, “Overwhelming smoker demand for reduced risk options suggests PREPs could become the next transforming tobacco market innovation... We expect successful innovation around a safer cigarette to reduce the likelihood of any acceleration in the two to three percent consumption rate decline” (Husten 2004).

These new tobacco industry products are not aimed at the highly addicted, hard core smoker, but rather the smoker who is contemplating quitting and youth and young adults who are not yet established tobacco users. If the public health community supports or is indifferent to the introduction of a nicotine maintenance strategy (whether it be products produced by the tobacco or pharmaceutical industry) because of its potential benefit to relatively few smokers, including legislation that

provides credibility for these products, then public health advocates will once again be on the defensive in terms of reducing tobacco use.

## **Losing momentum: Public health agencies' support of nicotine maintenance undermines promotion of tobacco abstinence and cessation**

**T**obacco companies are already in the nicotine maintenance business and pharmaceutical companies are poised to enter this market. The reason is clear: a large amount of money can be made by selling an addictive product to 46 million consumers concerned about their health. The justification for public health agencies to promote nicotine maintenance is less clear.

Public health proponents of nicotine maintenance as a public health strategy argue the following:

- There is a population of smokers who cannot or will not quit
- Addicted smokers need and will benefit from this alternative to quitting
- Nicotine maintenance as a public health strategy may reduce the net toll of tobacco on the population
- Nicotine maintenance messages would be presented in addition to, not instead of, the current prevention and cessation messages, and would not conflict with them
- Most states will never be able to or will take too long to achieve the kinds of reduction in tobacco use, consumption, youth uptake, secondhand smoke protection, and declines in tobacco-related diseases that California has achieved through its comprehensive tobacco control program. (In other words, "California is different.")
- Nicotine maintenance will help mentally ill tobacco users avoid the severest health consequences of smoking

These arguments do not make a compelling case for favoring a nicotine maintenance strategy. First, the CTCP does not accept the idea that there exists an unyielding set of obstinate or hopelessly addicted smokers who cannot or will not quit. Eight out of ten adult California smokers say they would like to stop smoking and more than 60% of them make at least one quit attempt each year (CDHS/TCS 2002). Furthermore, from 1990 to 2002, the percent of light smokers (those who smoked fewer than 15 cigarettes per day) increased 41%, while the percentage that smoked occasionally (not every day) rose 17% over the same time period (Gilpin 2004). Nationwide, millions of smokers would like to quit, and they retain

“if the social milieu includes frequent reminders that it is safe and easy to maintain a nicotine habit, then those same smokers will be more likely to continue using nicotine”

a willingness to try even after several relapses. Because most states, along with the federal government, have failed to adequately fund comprehensive tobacco control programs that have been proven to drive down tobacco use, it is simply too early to say that those smokers who want to quit will never quit.

The CTCP disagrees that addicted smokers need and will benefit from this alternative to quitting. We see a very real possibility that the “fallback option” of nicotine maintenance may result in an increase in the incidence of nicotine addiction, a decrease in quitting, and an increase in relapse. In a social milieu that encourages tobacco abstinence and cessation, smokers contemplating quitting may well succeed. On the other hand, if the social milieu includes frequent reminders that it is safe and easy to maintain a nicotine habit, then those same smokers will be more likely to continue using nicotine.

The CTCP believes that tobacco cessation and nicotine maintenance are contradictory strategies. We believe there would be harmful consequences if public health programs were to communicate a message such as, “the best thing you can do for your health is quit, but if you cannot quit, switch to smokeless tobacco or another alternative nicotine maintenance product.” Promoting the co-existence of tobacco cessation and nicotine maintenance strategies ignores the complexity of how product marketing is received and acted upon by tobacco users and potential users, let alone policy makers who are in a position to allocate resources and enact policies that regulate smoking and the sale and promotion of tobacco products. Insufficient analysis has been given to the impact such marketing would have in terms of the following:

- Decreasing the motivation of smokers to make quit attempts
- Increasing tobacco use initiation by young people
- Undermining the impact secondhand smoke policies have on increasing quit attempts and decreasing tobacco consumption
- Undermining the adoption of policies that regulate the sale, distribution and marketing of tobacco products aimed at decreasing tobacco use initiation and cues to use tobacco
- Undermining enforcement and resource allocation for enforcement of tobacco control policies
- Undermining investment in comprehensive tobacco control programs whose goal it is to promote tobacco use cessation versus promoting long term addiction to a “safe” form of nicotine
- Maintaining the improvement in health outcomes (e.g., lung cancer and heart disease declines) as a result of comprehensive tobacco control programs (i.e., clean indoor air policies)

While California and several other states have demonstrated that comprehensive tobacco control programs work, most states and the federal government have

failed to adequately fund these programs. Additionally, many states have failed to implement basic public health measures to protect all workers and the public from exposure to secondhand smoke in the work environment and other public settings. Thus, while significant progress has been made, there continues to be an urgent need for well-funded tobacco control programs.

Ironically, this failure of government to invest in comprehensive tobacco control programs and enact policies to protect workers and the public from exposure to secondhand smoke is used by proponents of the nicotine maintenance strategy. These proponents say that most states will never be able to or will take too long to achieve the kinds of reductions in tobacco use, consumption, youth uptake, secondhand smoke protection, and declines in tobacco-related diseases that have been achieved in California. They argue that these states need the nicotine maintenance strategy since their public health leadership has failed (although not necessarily from a lack of effort) to adequately help tobacco users quit or to protect nonsmokers.

The CTCP's response to this argument is that the nicotine maintenance strategy is unproven. There are no data to suggest a positive public health impact on quitting behavior and youth uptake, whereas comprehensive tobacco control programs are demonstrated to be effective at protecting and improving the public's health. Our scarce public health dollars must be applied to tobacco control interventions that work. In addition to diverting tobacco control resources away from proven methods, the nicotine maintenance strategy has an unknown financial cost which public and private insurers will surely be asked to cover.

The high rate of smoking among the mentally ill is also cited as a reason to support the nicotine maintenance strategy. The validity of this argument depends on a number of factors, including the definition of mental illness, the number of people characterized as mentally ill, the smoking prevalence rate among the mentally ill population, and the impact of the nicotine maintenance strategy on the population of mentally ill tobacco users.

As the definitions and diagnosis of mental illness have changed over time, so has the prevalence estimation of mental illness in the U.S. The current prevalence is best estimated at 20% of the U.S. population in any given year based on two national studies conducted in the early 1980s (the Epidemiologic Catchment Area Study) and the early 1990s (the National Comorbidity Survey) (U.S. Surgeon General 1999).

It is widely acknowledged that the smoking prevalence rate among the mentally ill is disproportionately high, and that tobacco is often used by the mentally ill for its antidepressant, mood modification and cognitive enhancement effects.

“The health care community must improve the care and treatment of mental illness, not look for quick fixes such as nicotine maintenance”

One frequently cited study estimated that 44% of cigarettes consumed in the U.S. were smoked by smokers with mental illness. This relatively small study (4,411 adults) defined mental illness very broadly including a wide array of anxiety, panic, phobia, bipolar and personality disorders; drug and alcohol abuse and dependence; and psychotic disorders such as schizophrenia and delusional disorders (Lasser 2000). In the Lasser study, a total of 28.3% of adults in 1991-1992 were reported to have mental illness in the past month, which is about two times higher than what is reported (15.7%) in another larger national study with 20,291 adults (Regier 1993). At this lower prevalence of mental illness, only about 25% of cigarettes consumed in the U.S. would be smoked by persons with mental illness instead of the 44% estimated in the Lasser study.

A more recent study of 43,093 adults in 2001-2002 reported that 34.2% of all cigarettes smoked in the U.S. were smoked by nicotine-dependent individuals with a comorbid psychiatric disorder (Grant 2004).

Even given the uncertainty of prevalence of the mentally ill in the U.S. and their actual cigarette consumption, smoking among the mentally ill is a significant problem. The question becomes, then, whether a nicotine maintenance strategy will benefit this population. The Lasser and Grant papers note that the tobacco industry targeted consumer segments with various psychological needs and sought to incorporate knowledge of personality characteristics into its brand research. These researchers conclude that it is important to focus smoking prevention and cessation efforts to counter this targeted marketing. These studies did not conclude that this population will never quit or should be offered a less hazardous form of nicotine maintenance.

The CTCP believes it is more effective to improve comprehensive tobacco control programs to provide more effective cessation, policy and media interventions for those with psychiatric conditions rather than promote nicotine maintenance as a public health strategy for those with mental illness. Equally, the CTCP does not believe that the lack of adequate mental health diagnostic and treatment services for those individuals using nicotine for its antidepressant, mood modification and cognitive enhancement effects is an adequate justification to endorse a nicotine maintenance strategy. The health care community must improve the care and treatment of mental illness, not look for quick fixes such as nicotine maintenance.

The CTCP concludes that whether nicotine maintenance messages are conveyed by the public health community, tobacco companies or the pharmaceutical industry, they will likely legitimize nicotine addiction. In doing so, these messages will decrease motivation for quitting, decrease quit attempts, slow declines in tobacco cessation, increase the rate of youth initiation, and undermine the effectiveness and investment in comprehensive tobacco control programs that seek to denormalize tobacco use and promote cessation.

## Bringing it home: Nicotine maintenance threatens comprehensive tobacco control programs

The CTCP has demonstrated that an adequately funded comprehensive tobacco control program will drive down tobacco use. We demonstrated that eliminating indoor smoking, raising the tax on tobacco products and earmarking a portion of the revenues for tobacco control programs, countering the tobacco industry's messages, and increasing the availability of cessation services reduces tobacco use initiation, increases quitting, and reduces overall tobacco consumption. California data (CDHS/TCS 2004) show the following:

- Per capita consumption of cigarettes has declined by more than 60% since 1988
- Adult smoking prevalence has declined by 17% since 1996
- Youth smoking prevalence among 8th graders has declined by more than 60% from 1996 to 2004
- 96.4% of Californians reported working in a smoke-free environment in 2002
- 83% of smokers and 93% of nonsmokers believe that any exposure to secondhand smoke can be harmful to your health (Field Research Poll 2004)
- Lung and bronchial cancers have declined at three times the rate of the rest of the nation
- The incidence of six of nine tobacco related cancers is lower in California than the rest of the nation

These successes are not unique to California. Nationwide, youth smoking, the initiation of tobacco use, adult smoking and overall tobacco consumption are declining. Nor is this progress solely a recent phenomenon. Both Dr. Gary Giovino and Dr. John Pierce noted the historic declines in U.S. per capita cigarette consumption in their presentations at the *Seduction of Harm Reduction Summit*. Per capita cigarette consumption in the U.S. peaked in the early 1960s and has steadily declined since. In 2000, per capita cigarette consumption was 53% lower than it was in 1964 (United States Department of Agriculture 2001). These declines over the past 40 years demonstrate that the public health community has achieved considerable success in reducing smoking. There is no reason to believe that California and the U.S. will not experience further declines in cigarette consumption at rates even greater than we have seen in the last 40 years given a continuing increase in state tobacco taxes, passage of clean indoor air laws, and public support for keeping tobacco out of the hands of youth.

“a smoker’s motivations to quit are reduced when solutions are offered to make smoking more palatable”

The CTCP believes that educating people about the dangers of secondhand smoke exposure and creation of smoke-free environments are fundamental to motivating smokers to quit, decreasing cigarette consumption, and making it easier for smokers to remain tobacco-free. In his presentation at the *Seduction of Harm Reduction Summit*, Dr. Shu-Hong Zhu emphasized that quitting takes effort. Frequently, a tobacco user makes several attempts before successfully quitting. Dr. Zhu noted that smoke-free policies along with social and cultural norm changes such as a smoking ban in the home can motivate people to quit and help them avoid relapse (Zhu 2004). The CTCP agrees with Dr. Zhu’s observation and believes that if a nicotine maintenance strategy were introduced into the social norm change/cessation strategy mix, tobacco users would be hindered from making serious quit attempts or from making repeated attempts if they are at first unsuccessful.

One of the strengths of the CTCP over the years has been the consistency of our message; because of our social norm change strategy, Californians understand that smoking hurts everyone—the individual, the family, and the community. Every aspect of the CTCP promotes the idea, “Don’t start. If you smoke, quit.” Some proponents of nicotine maintenance have mischaracterized our message as “Quit or die.” They would prefer the public health community to say, “If you cannot quit, at least switch to a possibly safer but admittedly still harmful form of nicotine addiction.” The CTCP understands that quitting can be extremely difficult; it can take many quit attempts. We support cessation, and our message to smokers is clear and unequivocal: “For the sake of your health and the health of those around you, quit.”

Quite simply, California’s denormalization strategy would not have been as effective at reducing the number of smokers or reducing the daily number of cigarettes smoked if it had promoted a nicotine maintenance product. Even if the CTCP had adopted a nicotine maintenance product as only one component of its comprehensive program, the impact would have had troubling implications for California smokers and overall morbidity and mortality. As indicated by Dr. Zhu, a smoker’s motivations to quit are reduced when solutions are offered to make smoking more palatable.

## **Giving the OK: Criteria to be met prior to public health endorsement of nicotine maintenance**

**P**ublic health agencies must ask themselves this question: Under what conditions, if any, would it be appropriate for the U.S. public health community to encourage current tobacco users who cannot or will not quit to switch to nicotine maintenance products that may be less harmful than other tobacco products they are using? Given the disastrous history of light cigarette use

over the past 40 years, the CTCP will not endorse this current manifestation of nicotine maintenance as a viable public health strategy until a strict set of criteria are met.

The CTCP proposes that the public health community strongly and unequivocally oppose the marketing of any proposed nicotine maintenance product until sufficient scientific evidence demonstrates that its use will:

1. Not slow the rate of decrease in youth uptake of cigarettes nor increase youth initiation of smoking or use of smokeless tobacco products
2. Not decrease tobacco use quit attempts nor successful cessation
3. Not increase relapse of former tobacco product users
4. Not undermine support for, or conflict with, comprehensive tobacco control program efforts
5. Not undermine support for tobacco control policy advances
6. Be restricted to an identifiable population of tobacco users who are indicated as likely to benefit from it
7. Be confined to tobacco users, and no others

Under one possible scenario, the determination of a product's satisfaction of the above criteria could be placed under the purview of a national scientific review panel dedicated solely to this purpose. For example, the scientific review panel could be appointed by the Centers for Disease Control and Prevention, Office on Smoking and Health and the NCI. Members of the scientific review panel would have to be free from conflict of interest (i.e., never having received funding from tobacco or pharmaceutical companies and having no financial interest in a tobacco or pharmaceutical company or subsidiary). Additionally, the composition of the panel would need to be equally balanced among those with expertise in public health and individual health.

## **Federal regulation: placing limits on nicotine maintenance**

**I**n an ideal world, the criteria listed above for our endorsement of nicotine maintenance as a viable public health strategy would be met before any so-called "reduced harm" product became available to consumers. But, the current situation is far from ideal.

At the present time, science is unable to determine whether or not a nicotine maintenance product satisfies our endorsement criteria. We lack the scientific capacity to:

- identify biomarkers predictive of disease risk,

- determine the threshold of toxicant exposure that allows a claim for reduced disease risk,
- determine disease risk given the individual variability that is observed in response to using these products, or
- understand disease risk resulting from variable patterns of tobacco use, introduction of new toxicants and novel combinations of toxicants.

In addition, market and political forces beyond the control of public health groups are at play. Tobacco companies are already marketing products that claim to be lower in risk or toxicant exposure than conventional combustible cigarettes. Pharmaceutical companies are researching medicinal nicotine maintenance products. USST and even some members of the public health community are advocating for the promotion of smokeless tobacco or low nitrosamine snus as a safer alternative to conventional combustible cigarettes. Some public health groups are working with elected officials to regulate tobacco products characterized as having fewer carcinogens or as being “safer.”

### **The IOM Report: The federal government weighs in on the debate**

Prompted by the tobacco industry’s research, development, and marketing of “reduced harm” products, the FDA contracted with the Institute of Medicine (IOM) in 1999 to explore possible ways to meaningfully regulate these new products and messages.

Part of IOM’s charge was to “lay out scientific methods and standards by which these so-called harm-reduction products could be assessed” (National Academies 2001). To facilitate this process, the IOM established the Committee to Assess the Science Base for Tobacco Harm Reduction. This 12-member committee developed a framework for assessing “tobacco products that may be less harmful or pharmaceutical preparations that may be used alone or concomitantly with decreased use of conventional tobacco” (National Academies 2001).

In its report, *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction*, the committee defined harm reduction as decreasing the burden of death and disease “without completely eliminating tobacco and nicotine use” (IOM 2001). The committee concluded that “harm reduction is a feasible and justifiable public health policy” if it is implemented in a way that ensures the following:

- Manufacturers have incentive to develop and market products
- Consumers are fully informed
- Marketing and labeling are regulated
- Research is conducted

- Harm reduction is a component of a national comprehensive tobacco control program

The committee's recommendations on how to implement harm reduction are organized into eleven Regulatory Principles. Several of these Regulatory Principles give cause for concern:

**Regulatory Principle 4** would permit manufacturers to "market tobacco-related products with exposure-reduction or risk-reduction claims" provided that:

- there is sufficient "scientific evidence... that the product *substantially reduces exposure to one or more tobacco toxicants*" [emphasis added], and
- if a risk reduction claim is made, the product can *reasonably be expected to reduce the risk* of one or more specific diseases or other adverse health effects..." [emphasis added]

In other words, the committee would permit manufacturers to make reduced exposure claims for any nicotine maintenance product provided there is evidence that the product substantially reduces user exposure by as little as a single tobacco toxicant as compared to "conventional tobacco products" (presumably cigarettes, although the term is never defined in the report). This Regulatory Principle seemingly ignores the reality that consumers often interpret "reduced exposure" messages to mean "reduced risk."

**Regulatory Principle 3** allows results of "appropriate toxicological testing in pre-clinical laboratory and animal models as well as appropriate clinical testing in humans" as justifications for making a reduced risk claim for a product. This standard appears to allow health-related claims based solely on animal and toxicology studies.

**Regulatory Principle 7** recommends that no prior regulatory approval be required for new or existing products that "can reasonably be expected" to cause no more adverse harm than "conventional tobacco products." Manufacturers of new products would only have to certify that the product "could not reasonably be expected to increase the risk" of tobacco-related health problems "compared to similar conventional tobacco products." This Regulatory Principle is cause for alarm, for it appears to define the harm caused by today's "conventional tobacco products" as the gold standard.

The troubling aspects of the IOM report go beyond the issues raised by each Regulatory Principle. Because of its clinical focus on the medical treatment of individuals, the report works poorly as a set of recommendations for a public health agency (Hirschhorn 2002). For example, the report contends that "current knowledge of the dose-response relationships is sufficient to support risk reduction

“The report itself concedes that “reduced exposure... does not necessarily assure reduced risk to the user or reduced harm to the population”

through exposure reduction as a goal for *the individual* through the use of these various products” [emphasis added] (IOM 2001). The emphasis is on an individual’s toxicant exposure, not population disease effects.

The report itself concedes that “reduced exposure... does not necessarily assure reduced risk to the user or reduced harm to the population.” Furthermore, the report acknowledges that “the only way to evaluate the harm reduction value of PREPs is to monitor the health outcomes of users compared to appropriate control groups over an extended period of time” (IOM 2001). However, instead of requiring large and strenuous clinical human trials that might answer questions about a product’s likely health effects before approval is given to market it with claims of reduced risk, the IOM report recommends, in **Regulatory Principle 6**, only that the manufacturer be required “to conduct *post-marketing surveillance* and epidemiological studies as necessary to determine the short-term behavioral and long-term health consequences” [emphasis added]. In other words, the report seems to say, “approve the product and see what happens.”

This strategy would use unsuspecting smokers as guinea pigs to determine a new product’s safety. Post-marketing surveillance strategies such as the one recommended by the IOM report rely on manufacturers to oversee the studies or rely on passive reporting systems, and the results of such studies are often unsatisfactory, as shown by the recent example of the drug rofecoxib (Vioxx) and cardiovascular disease (FDA 2005).

The IOM report’s Regulatory Principles would require little of the tobacco industry. They would basically institutionalize the status quo for conventional tobacco products. The report seems to assume that public information about the ingredients of PREPs is all that is needed to address the threat to public health posed by these products and the massive machinery of their marketing and promotion. The CTCP believes that public information alone is severely inadequate, and the CTCP is not alone in this regard. Dr. Gary Giovino, an IOM Committee member, stated at the *Seduction of Harm Reduction Summit* that he thought the “Regulatory Principles of *Clearing the Smoke* are far too weak.” (Giovino 2004).

The tobacco industry’s reaction to the IOM report was largely positive (Fairchild 2004, Gori 2002). And, no wonder: the IOM report’s Regulatory Principles would bring tobacco products under the regulatory purview of the FDA without asserting any control over their manufacture, distribution, or marketing (other than perhaps accurate labeling). The acceptance of current tobacco products and their present marketing under this regulatory structure could be considered tantamount to FDA endorsement, and might give the industry its much-desired safe harbor against product liability claims.

It is no surprise, then, that the tobacco industry and its allies have interpreted the IOM report as the rebirth of “safer cigarettes” and are using it as a roadmap for the development of new products (Fairchild 2004). For example, Philip Morris is carrying out research and development of a new reduced exposure cigarette product called Marlboro UltraSmooth. One of their research objectives is to address Regulatory Principles 1, 2, 3, 7 and 8 (Gaworski 2005).

The CTCP finds the IOM’s report to be flawed: its proposed Regulatory Principles are weak, and its conclusions unsupported. In several places, the report even seems to disown its own recommendations. It states that “harm reduction is a feasible and justifiable public health policy,” yet concedes that “harm reduction through the use of PREPs is not yet convincingly demonstrated” (IOM 2001). It acknowledges that the population impact is unknown, but “the net impact on the population health could, in fact, be negative” (IOM 2001). It admits that “no panel of markers can be utilized currently to evaluate the health effects of PREPs” (IOM 2001) and that the knowledge base is “inadequate” to perform a “formal risk assessment” of such products (IOM 2001).

What the CTCP finds most disturbing is the IOM report’s seemingly open invitation to the tobacco industry to foist another “safer cigarette” episode onto the American public. The Regulatory Principles equate reduced tobacco toxicant exposure with tobacco harm reduction, while conceding that reduced exposure may not actually reduce tobacco harm. The report underestimates the danger that the public will likely misinterpret toxicant exposure claims as an indication of improved safety.

The IOM report’s Regulatory Principles are built on a leap of faith that a new generation of nicotine maintenance products will be likely to reduce harm and therefore should be allowed on the market and even encouraged. Public health policy should not be made on the basis of an unfounded assumption that scientific research will yield a “less hazardous cigarette.” Lastly, post-marketing surveillance and epidemiological studies are inadequate to assess in a timely manner the very real danger of unintended, potentially fatal effects that PREPs pose for millions of Americans. In short, the IOM report fails to make a compelling case for the nicotine maintenance strategy.

### **A higher standard: California demands a stricter set of regulatory guidelines**

The CTCP believes that any regulatory framework governing tobacco products must be significantly more strenuous than the Regulatory Principles proposed in the IOM report. Therefore, the CTCP proposes several recommendations for regulating nicotine maintenance products that will help protect the nation against possible unintended consequences from the promotion and dissemination of these products. These regulatory provisions will also help the public understand that,

“The CTCP finds the IOM’s report to be flawed: its proposed Regulatory Principles are weak, and its conclusions unsupported”

because tobacco products are inherently dangerous and have no beneficial use or purpose, they are radically different from other ingested consumer products.

The broad topic of tobacco regulation involves not just the regulatory standards themselves, but also the question of which governmental agency is best suited to promulgate and enforce those regulations.

Currently, federal regulation of tobacco products consists of piecemeal regulations and advisory publications such as the Surgeon General reports on the dangers of tobacco, warning labels on packaging, and the television ban on tobacco advertising. Many members of the public health community have called for placing the regulation of tobacco products under the purview of the FDA. Enabling legislation for FDA regulation of tobacco has been introduced in Congress, but has not been enacted as of the date of this writing. Additionally, nicotine replacement therapy products used in cessation, such as transdermal patches and nicotine gum, are regulated as drugs by the FDA.

As explained below, the CTCP strongly opposes the idea that the FDA is the best federal agency to regulate tobacco products.

## Recommendations related to all tobacco and nicotine products

### **Recommendation 1: Establish a federal Tobacco and Nicotine Control Administration.**

A federal Tobacco and Nicotine Control Administration would be responsible for (a) administering a national program to decrease tobacco use and nicotine dependence; (b) regulating nicotine products and their promotion; (c) establishing exposure standards; and (d) funding independent post-marketing surveillance and studies. This agency would be charged with first and foremost protecting the public's health, establishing that regulation of nicotine products does not create a safe harbor from future litigation, and given broad authority to institute timely changes to regulations as new information about the safety of these products in clinical or real world settings emerged.

*Justification:* An agency other than the FDA should regulate tobacco and nicotine products because tobacco products do not fit within the mission of the FDA, which is to ensure that drugs and medical devices are safe and efficacious. Placing the regulatory oversight of tobacco products within the purview of the FDA may give consumers the perception that tobacco products are benign. It may also undermine the FDA's credibility as a public health agency that ensures the drugs and medical devices it approves are safe and have a health benefit.

**Recommendation 2:**

**Prohibit tobacco companies, pharmaceutical companies and others from making implicit or explicit reduced risk claims for their products unless the Tobacco and Nicotine Control Administration determines that there is substantial scientific evidence to support the claims.**

*Justification:* Claims of reduced risk for a product need to be substantiated with studies funded and conducted by organizations other than the company manufacturing the product and verified by an impartial agency with no financial gain. Even marketing messages that do not make explicit claims of reduced risk may be interpreted by the consumer as such.

**Recommendation 3:**

**Require independent post-marketing surveillance and studies to determine short-term and long-term consequences of tobacco and other nicotine maintenance products including medicinal nicotine to be funded by the tobacco and pharmaceutical companies and administered by the Tobacco and Nicotine Control Administration.**

Tobacco and pharmaceutical companies should be required to provide funding to the Tobacco and Nicotine Control Administration to administer and conduct independent post-marketing surveillance and studies to determine short-term and long-term consequences of reduced harm tobacco products, non-combustible nicotine delivery devices, and medicinal nicotine products. Health consequences to the user and the population need to be monitored including: the impact on initiation and cessation (including quit attempts and relapse), the impact on enactment of community norm change tobacco control policies (e.g., secondhand smoke, restrictions on sale and distribution of tobacco products, restrictions on marketing), and funding for comprehensive tobacco control programs and enforcement of tobacco control laws.

*Justification:* The public health system needs to understand the impact nicotine maintenance products (produced by either tobacco or pharmaceutical companies) have, not just on the health of individuals, but also on public health gains or harm to existing proven public health strategies such as comprehensive tobacco control programs. The value of nicotine maintenance products needs to be examined in comparison to public health outcomes (quit attempts, cessation, uptake, secondhand smoke exposure, incidence of tobacco-related diseases) and health care system costs. The cost of medicinal nicotine maintenance products also needs to be examined in terms of its impact on public and private health care insurers who will be asked to cover the cost of these drugs.

**Recommendation 4:**

**Within 10 years, establish and enforce a single toxicant exposure standard for each type of tobacco and nicotine product that is based on actual use by consumers and on in vitro cell and in vivo animal studies to examine genotoxicity, cytotoxicity, mutagenicity, and tumor promotion of identified toxicants.**

*Justification:* The ability of science to actually determine toxicant exposures and set standards is in its infancy and the exact mechanism of some of the toxicants is not clearly understood. Possible effects from the long-term use of nicotine are not clearly understood either. Some studies indicate it may act as a tumor promoter or angiogenic agent. Understanding the impact of toxicants and setting exposure standards would assist with the regulation of tobacco products. For example, there could be greater regulation of the sale and promotion or higher taxes imposed on those products that pose a greater health risk.

## Recommendations related to modified cigarettes and cigarette-like products

**Recommendation 5:**

**Prohibit tobacco companies from advertising, promoting or labeling their products with claims of reduced exposure to toxicants.**

*Justification:* The public misinterprets reduced exposure messages as being the equivalent of reduced health risk. However, reduced exposure does not necessarily assure reduced risk to the user or reduced harm to the population. Since it has not been established that reduced exposure to one or more toxicants translates into improved public health gains, these types of messages, whether explicit or implicit, should be prohibited.

**Recommendation 6:**

**Prohibit tobacco companies from advertising, promoting or labeling their products with claims of reduced health risk based upon reduced exposure to one or more toxicants.**

*Justification:* There is no evidence that an individual will be at reduced risk for developing cancer, heart disease or respiratory diseases merely by reducing exposure to one or more toxicants in cigarette and cigarette-like products, nor is it known how consumers will use these products in the real world. For example, with light cigarettes, smokers covered up the vent holes on the filters. Modified cigarettes and cigarette-like products (or any other type of PREP) should not be permitted to be promoted as reduced risk products or as substitutes for conventional combustible cigarettes unless these products are able to prove that

they demonstrably reduce overall disease risk, not merely reduce exposure to one or more toxicants.

**Recommendation 7:**

**Prohibit tobacco companies and others from using the fact that their products are regulated by the Tobacco and Nicotine Control Administration, the FDA or any other federal agency, as a defense in future liability litigation.**

*Justification:* Regulatory government oversight of a product is not the equivalent of endorsement of that product. In fact, regulatory oversight is usually authorized because the product poses a public health or safety issue. Tobacco products are complex chemical products. Individual differences in exposure, consumer use of the product, and genetics influence the health impact on the user and are unknown. The federal government must have the full menu of regulatory options available should any product prove to be unsafe.

**Recommendation 8:**

**Include “anti-preemption language” in any federal legislation aimed at regulating tobacco products.**

*Justification:* Federal regulations must permit state and local standards for the sale, marketing and product parameters to go beyond those set at the federal level; federal legislation should set a floor, not a ceiling. Local and state governments should be given the autonomy to set more stringent controls because local and state governments are more progressive and innovative in comparison to the federal government when it comes to protecting the public’s health from tobacco use (e.g., earmarking tobacco taxes for comprehensive tobacco control programs, clean indoor air legislation, MSA, fire safe cigarettes, etc.). Local and state governments should be given the flexibility and explicit authority to set higher standards on the constituents, marketing and sale of tobacco products than those at the federal level. The federal government should embrace using the local and state levels as policy labs to test new solutions to vexing problems.

## Recommendations pertaining to smokeless tobacco products

**Recommendation 9:**

**Prohibit federal public health agencies, including the Department of Health and Human Services, the FDA and the FTC, as well as research institutions and state public health departments receiving federal funds for tobacco control research and interventions, from sanctioning or promoting smokeless tobacco as a safer alternative to conventional combustible cigarettes.**

*Justification:* While smokeless tobacco is not associated with lung cancer and chronic obstructive pulmonary disease as are conventional combustible cigarettes, there is insufficient evidence to suggest that there would be a public health benefit in terms of a reduction in tobacco-related cancers, heart disease and respiratory disease from promoting such a message. Such messages may encourage heavier usage of smokeless tobacco or greater initiation. Furthermore, promotion of a message that says, "If you cannot quit, switch to smokeless tobacco" will undermine consumer trust in public health. It may cause consumers to become suspicious of other public health messages such as, "Secondhand smoke causes cancer." Additionally, this message could undermine the effectiveness of secondhand smoke protection policies in terms of their ability to promote decreased consumption and prompt quit attempts.

**Recommendation 10:**

**Do not permit smokeless tobacco manufacturers to advertise their products as safer than cigarettes.**

*Justification:* Although there are fewer carcinogens and none of the respiratory illnesses associated with cigarettes, smokeless tobacco use does give rise to health risks. Smokeless tobacco use causes oral-cavity cancer and may cause pancreatic cancer. Products such as snus still contain unacceptably high levels of potent carcinogens and there is considerable debate as to the ecological evidence from Sweden regarding the health value of snus. Furthermore, many in the tobacco control community share concerns about the concurrent use of cigarettes and smokeless tobacco as well as the impact increased smokeless tobacco use would have on undermining the cessation impact of clean indoor air policies.

## Recommendations pertaining to medicinal nicotine maintenance products

**Recommendation 11:**

**Require all medicinal nicotine maintenance products to meet current FDA requirements for the approval of new drugs and medical devices.**

*Justification:* Currently, the federal government has no regulatory power over the manufacture of tobacco products; on the other hand, nicotine products manufactured by pharmaceutical companies must meet strict safety and efficacy standards. Proposals have come from industry sources to lessen or erase this regulatory disparity by weakening the standards for medicinal nicotine. However, the CTCP strongly disagrees with these proposals and believes that the answer is to raise regulatory standards for tobacco rather than to lower the regulatory standards governing the sale, packaging, and marketing of medicinal nicotine maintenance products.

**Recommendation 12:**

**Require that medicinal nicotine maintenance products be approved for use only under a physician's prescription.**

*Justification:* Medicinal nicotine maintenance products should be indicated only for the most completely addicted who are suffering from a health condition that would be significantly improved by shifting from smoking to medicinal nicotine (e.g., a smoker suffering from chronic obstructive pulmonary disease). Medicinal nicotine maintenance products may have a role in the treatment of heavily addicted persons whose health is being compromised by continued use of conventional combustible cigarettes. By requiring these products to be dispensed only under a physician's prescription, there is greater assurance that the products will be used as intended (and not mixed with tobacco products) and that there would be monitoring of treatment and assistance to help the patient quit before or after prescribing the product.

**Recommendation 13:**

**Prohibit direct consumer advertising and marketing of medicinal nicotine products.**

*Justification:* Direct consumer advertising of prescription products creates a perceived need and demand for those products. Pharmaceutical companies have far more resources to promote their products than public health programs have to conduct media campaigns to motivate cessation and advertise their cessation quitlines. If pharmaceutical companies were to directly advertise medicinal nicotine maintenance products to the public, the media could be overwhelmed with messages promoting long-term nicotine use. Such marketing may decrease quit attempts and increase youth tobacco initiation.

## Conclusion

“Smoking cessation is rarely easy; recommending the use of nicotine maintenance products to tobacco users who think they cannot or do not want to quit will weaken their resolve to keep trying even after multiple relapses”

The California Tobacco Control Program opposes adoption of a nicotine maintenance strategy because the nicotine maintenance approach to tobacco harm reduction has a very high potential for *increasing* tobacco-related morbidity and mortality. There is currently no scientific evidence demonstrating that public health endorsement of any nicotine product for long-term use would yield a public health benefit. The ultimate outcomes of the nicotine maintenance strategy are unknown, as is the time frame in which measurable reductions in tobacco-related cancers, cardiovascular disease and respiratory disease might be expected. Additionally, the nicotine maintenance strategy has an unknown financial cost which public and private insurers will certainly be asked to cover.

The CTCP opposes adoption of a nicotine maintenance strategy because it is a competing and contradictory alternative to quitting. We believe that promoting the use of a nicotine maintenance product as a “second best” alternative to quitting will inevitably weaken the efforts of federal, state, and local comprehensive tobacco control programs aimed at preventing uptake and promoting cessation of tobacco use. Smoking cessation is rarely easy; recommending the use of nicotine maintenance products to tobacco users who think they cannot or do not want to quit will weaken their resolve to keep trying even after multiple relapses. That resolve is crucial for successfully quitting, as many former smokers well know. Public health programs can not promote a potentially less harmful or dangerous type of nicotine product as a substitute for harmful nicotine products without seriously compromising their efforts to rid society of all harm caused by nicotine products.

The CTCP opposes adoption of a nicotine maintenance strategy because of its high potential to undermine interventions that are well documented in terms of their effectiveness and public health benefit (e.g., tobacco tax increases, comprehensive tobacco control programs that denormalize tobacco use through policy interventions, and counter-marketing media campaigns). These interventions have demonstrated their ability to reduce adult tobacco use and consumption, reduce tobacco use initiation, and protect non-smokers from secondhand smoke. In California, where a comprehensive tobacco control program has been in place for 15 years, the incidence of several tobacco-related cancers is also on the decline. We have not hit an impenetrable wall of hard-core smokers. If anything, Californians appear less addicted and more poised than ever to quit smoking.

The CTCP’s overwhelming conclusion is that the public health establishment should actively oppose, and not just refuse to endorse or promote, the marketing of nicotine maintenance products that are supposedly less harmful than conventional combustible cigarettes, until truly compelling evidence demonstrates that a policy in support of nicotine maintenance will benefit public health.

We recognize, however, that at the present time, researchers lack the capacity to determine how well nicotine maintenance products meet our endorsement criteria. At the same time, the tobacco industry and the pharmaceutical industry are already using the nicotine maintenance approach to sell existing products or devoting research and development resources to new products that will be marketed with a “harm reduction” message. In addition, well-respected members of the scientific and public health communities are advocating federal regulation of so-called “harm reduced” tobacco products. To that end, we have proposed a number of regulatory guidelines that will help ameliorate and contain the unintended consequences that will likely arise from the promotion and distribution of nicotine maintenance products.

Experience tells us that many of our recommendations for regulation will be difficult to achieve. The challenges are both political and scientific. Historically, both the tobacco and pharmaceutical industries have been well positioned to lobby for legislation that promotes their business interests. In addition, science is not yet able to adequately measure toxicants in tobacco products or to measure the individual or public health impact of a nicotine maintenance strategy.

In order for federal regulation to provide meaningful protections against the possible harmful consequences of the nicotine maintenance strategy, the nation needs well-funded public health surveillance systems to:

- monitor the individual and public health impacts of using nicotine maintenance products,
- monitor the impact of nicotine maintenance strategies on comprehensive tobacco control program strategies and funding, including the enactment of tobacco control policies, particularly secondhand smoke policies which have been demonstrated to decrease tobacco consumption and promote quit attempts, and
- monitor the impact of communicating harm reduction/nicotine maintenance messages on different groups of people, including smokers vs. non-smokers, and those at high risk for tobacco uptake vs. those at low risk.

The CTCP acknowledges that the harm reduction debate is a heated one; it did not begin, nor will it end, with this paper. Continuing changes in the scientific and political environment will help shape the decisions made by the public health community, policy makers and corporations on whether to deploy a nicotine maintenance strategy at the 46 million smokers in the U.S. We cannot afford to repeat the light cigarette disaster. We hope that the recommendations and justifications provided in this paper are given serious consideration by tobacco control advocates nationwide.

## Appendix A: Members of the Harm Reduction Task Force

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## Appendix B:

### A selection of publications that refer to harm reduction as a tobacco control strategy

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