# A Reflection On Alternative Nicotine Delivery Systems

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There has been a recent trend among some of the tobacco control community to advocate a new emphasis on the development and promotion of alternative nicotine delivery system (ANDS). This trend was exemplified by a conference held in Toronto in early 1997.[1] The underlying premise of many advocates of ANDS is the existence of a very large number of nicotine addicts who receive their dose of nicotine through tobacco products, only a fraction of whom will be able to quit smoking. A further assumption of this harm reduction approach is that providing nicotine to these addicts in a delivery vehicle which does not involve ingesting tobacco could dramatically reduce the aggregate health consequences of tobacco use. One proponent of ANDS cautions "unless we establish an aggressive harm reduction strategy that promotes the use of alternative nicotine delivery products our campaign may not achieve our goal of reducing [smoking] prevalence to 15%."[2]

ANDS proponents suggest a market-driven solution to tobacco use could be found in the introduction of new and safer nicotine consumer products. To expand the availability of new delivery systems for nicotine, they are suggesting changes by government regulators, nicotine product manufacturers, advertisers and retailers. Governments are urged to reduce the red-tape faced by pharmaceutical companies. "[S]ociety poorly regulates the cigarette and over regulates nicotine gum. The proper regulatory response is to implement a strategy that levels the regulatory playing field between the cigarette and AND products."[3] Pharmaceutical companies are urged to be more aggressive marketers. "I think it important that drug manufacturers, who will profit from less cigarette sales, pursue this in their advertising and that they lift any voluntary restraints they have from directly competing with tobacco products and attacking the tobacco industry." [4] "We can give consumers a choice, and manufacturers an incentive to compete for the nicotine market…we can allow private enterprise to unleash its creativity in order to address our leading cause of preventable death."[5] The prospect of nicotine products being "widely available, at least in a basic maintenance dose, in such places as overnight convenience stores." [6] is suggested as a progressive step. Advertisers of new nicotine products are reminded that the "successful ANDS product will not forget pleasure."[7]

Smokers may be less convinced than these theorists that today's alternative nicotine products are satisfactory substitutes for cigarettes. Currently, there is no widely available delivery system which provides nicotine to the drug user in ways which approximate cigarette smoke. Gums and nicotine patches do not provide the dramatic peak in serum nicotine levels which the smoker's brain has come to crave. To develop and test such systems and to establish their safety and efficacy as part of an ANDS strategy will require considerable investment of resources. Subsequently, extensive marketing will be necessary to convince smokers to switch to the new systems. The economic investment required to launch such a strategy would 'eclipse' the current investment by western governments in preventing nicotine use. Not surprisingly, the resources needed to launch alternative nicotine products are possessed by the tobacco industry, which has already taken dramatic movements in this direction in the development of the Eclipse cigarette by RJ Reynolds.

There are a number of very serious issues which need to be considered before the tobacco control community embraces an alternative nicotine delivery strategy. Until now, we have operated from the premise that nicotine addiction is a disease which young people develop as a result of a number of external influences. The tobacco industry has worked very hard to addict children through aggressive advertising. We have told governments that the industry must be kept away from children, through total bans on advertising and sponsorship. Those in the industry have been discredited as merchants of death, a reputation richly deserved. In industrialized societies, tobacco use has been eliminated from an ever expanding list of public places, and the effect is that the exposure of children has been reduced.

Adopting alternative nicotine delivery as a major emphasis will require a complete reversal of our thinking. We would have to accept that rather than being a preventable disease, nicotine addiction is a fundamental human characteristic which we are powerless to change. The role of the health community will be shifted from curing or preventing nicotine addiction to ensuring that it is satisfied in the least toxic form possible.

As such alternative nicotine products are now and will increasingly be provided by tobacco companies, we will have to develop a new understanding of the social and economic role of this industry. We will have to accept tobacco companies as legitimate businesses, and their managers as honest business people. We will have to trust their actions and be at least passive partners in their research, development and marketing of new tobacco products. The spectre of the health community approaching government arm in arm with the tobacco industry is one which I found profoundly disturbing, even as I know that it has already happened in Canada in connection with the Eclipse cigarette.

Nicotine, of course, is one of the reasons people smoke. In the process of receiving their dose of nicotine, addicts are exposed to thousands of toxic compounds produced from burning tobacco leaves. Nicotine is probably not directly responsible for the cancers which tobacco causes, or the respiratory diseases. There is evidence that nicotine is directly responsible for some of the cardiovascular consequences of tobacco use. While decided preferable to tobacco smoking, pure nicotine ingestion cannot be considered to be innocuous. Those products developed by the pharmaceutical industry, including nicotine gum and patches, provide nicotine in what is probably the safest possible form, and some addicts rely on this products for very extended periods of time. However, for the majority of smokers, the nicotine is not produced in a satisfactory format, since the 'hit' of nicotine supplied by smoking is not mimicked with these products.

The product furthest along in development to achieve the objectives of satisfactory nicotine delivery and harm reduction is RJ Reynold's Eclipse system, currently under development in many countries, including Canada. This product appears very similar to a cigarette, but heats the tobacco instead of burning it. The result is the delivery of nicotine in aerosol form to the smoker, with very little production of smoke. The nicotine delivery is the same as with cigarettes, including the sudden surges in serum level which many smokers require. The concentration of many toxic compounds is lower than with conventional cigarettes, but the concentration of carbon monoxide is higher.

The health advantages of the Eclipse system are far from proven. A detailed MEDLINE search of the medical literature from January 1994 to July 1997 turned up only one paper on the subject of tobacco-heating cigarettes. Interestingly, the paper was from the RJR Reynolds tobacco company, and compared the mutagenicity of the urine from smokers of regular cigarettes to smokers of a tobacco-heating cigarette.[8] While the urine of the test cigarette group contained lower levels of cancer-causing chemicals than the urine of regular smokers, these chemicals were still present in significant concentrations. There is no evidence whatsoever that tobacco-heating cigarettes are any safer than regular cigarettes. The tobacco industry may have data on this question, but until methodologically sound studies are published in peer-reviewed journals, we have no way of assessing the evidence.

There are high risks associated with introducing such a product to the market.

- Pregnant women might switch to Eclipse rather than quitting altogether. New research is documenting how nicotine and its metabolites cross the placenta and are excreted in breastmilk, suggesting that this may result in the addiction of infants at the very beginning of life, and predispose children to smoking or other forms of nicotine addiction.
- If allowed to market new alternative nicotine devices, there is good historic reason to believe that the tobacco industry would do so in a way which recruits children and youth. Such recruitment of a new generation would needlessly extend the pandemic of tobacco use well into the next millenium.
- Smokers may be discouraged from quitting, since they could switch to a 'safer' product.
- Former smokers could be recruited back to nicotine addiction in the belief that they could smoke with impunity.
- Initiatives to reduce smoking opportunities through bans on smoking in public and work places could be stalled.
- Smokers could be encouraged to continue smoking in their home, increasing their own tobacco consumption and providing role models for smoking to their children.
- The de-legitimization of tobacco and smoking could be stalled.

- A new smoking ‘fad’ could emerge.

Similarly, alternative nicotine products developed by the pharmaceutical industry cannot be assumed to be benign, in either their current or future forms. Whether delivered through patch, gums, inhaler or lollipop, nicotine is a powerful and toxic substance. The capacity of large segments of the population to become addicted to nicotine, to underestimate the health consequences of its use, and to hold strong beliefs about the benefits of its consumption (i.e. physical and mental alertness, weight loss), have already been established. There is an historical and established reluctance of governments to adequately regulate and control nicotine. There is no prima facie reason to believe that pharmaceutical companies will continue to resist lifestyle advertising and other promotional strategies to encourage the non-therapeutic long-term use of nicotine products.

There are a number of conditions which should be met before the health community further invests time and resources to proposals for alternative nicotine delivery systems. First, there must be sound scientific evidence that the products being promoted are safer. There must be a soundly predictable reduction in morbidity and mortality. Reliable estimates are needed of the number of smokers who can be moved to alternative nicotine systems. The economic cost of this market shift, and the impact on cessation should also be measured. Most importantly, reliable measures are needed of the lives saved by shifting smokers to new nicotine delivery systems. These estimates must be compared with the number of lives which could be saved by a comprehensive tobacco use reduction strategy using established policy tools (i.e. total advertising ban, dramatic price increases, access restrictions and effective education) and by developing new policy tools (i.e. changed legal status of tobacco, reduced availability of tobacco products).

In addition to epidemiological concerns, there are economic considerations which should weigh against the early adoption of an ANDS strategy. Shifting smokers to new nicotine products will divert funds theoretically available to campaigns to reduce tobacco use into a for-profit market of ANDS products. It is impossible at this point to predict the economic impact of a successful ANDS market. However, shifting the expenditures of only 1% of the Canadian smoking population to alternative nicotine products would involve a far greater private expenditure on maintaining nicotine addiction (approximately $80 million per year) than is currently allocated by public funds to reduce smoking or cure nicotine addiction ($10 million in federal Canadian expenditures in 1997-98).

Lessons on the market potential for – or consumer vulnerability to– new nicotine products may be found in the early Canadian experience with the nicotine patch. Between 1991 and 1993, new prescriptions for nicotine patches rose from 0 to over 600,000.[9] That is, almost 10% of Canadian smokers were recruited to try the patch in the second year of its marketing. Pharmaceutical manufacturers could not advertise the patch directly to consumers, although it was directly advertised to physicians and promoted to the general public through news and information media. In both direct and indirect promotion, the patch was represented as a therapeutic aid to smoking cessation. The boom market did not last long (by 1994 new prescriptions fell to 200,000), but not before one patch manufacturer was penalized for charging excessive prices for the product[10]. If 10% of all smokers can be moved without direct advertising to try an expensive product designed to help them quit, when only 48% of smokers declared themselves to be contemplating or preparing to quit,[11] how much larger is the potential market for substitute nicotine products which are advertised, affordable and accessible? What is the market for products which are better satisfy the symptoms of nicotine addiction? What is potential market for nicotine manufacturers if their products are not used therapeutically for short periods, but become part of a long-term drug use pattern?

A market-driven for-profit solution to tobacco use has no inherent economic superiority over a publicly-funded not-for-profit solution to nicotine addiction. The investment of transnational companies in a ‘harm reduction’ strategy which also builds a lasting commercial market for an addictive substance cannot, on health or economic grounds, be viewed as inherently superior to public investments in reducing smoking.

The development and particularly the marketing of new nicotine products must be taken out of the hands of the tobacco industry. This industry has proven itself incapable of restraining its activities, particularly in the recruitment of non-smoking populations, such as children. There is no reason to believe RJ Reynolds will market Eclipse with any greater respect for public health than it has marketed Camel cigarettes.

Changing emphasis from tobacco use initiation and prevention to concentrating on alternative nicotine delivery systems would require significant rethinking of our activities on tobacco control, and reallocation of resources and

expertise. Until convincing evidence is available that these products are indeed safer, and until control of their marketing and development has been taken out of the hands of the tobacco industry, this approach cannot be recommended. Nicotine addiction is not a fundamental human characteristic, but a tragic childhood disease which we should continue to work hard to prevent.

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1 Alternative Nicotine Delivery Systems. Harm Reduction and Public Health. This conference was jointly held by the Addiction Research Foundation, the Ontario Tobacco Research Unit and the American Society of Addiction Medicine on March 21-23, 1997./

2 Connolly, Gregory N. Closing the Gaps A public health agenda for nicotine harm reduction. Paper presented at the Conference on Alternative Nicotine Delivery Systems, Toronto, March 1997.

3 ibid.

4 ibid.

5 Sweanor, D. Alternative nicotine delivery as a harm reduction strategy – getting rid of the dirty syringe. Adapted from a paper used at a panel discussion oat the American Society of Addiction Medicine Conference, October 14, 1995 in Toronto.

6 Room, R. Control Systems for Pyschoactive substances. Paper presented at the Conference on Alternative Nicotine Delivery Systems, Toronto, March 1997.

7 Kozlowski, L. "Better, smoother and not a cough in a carload." Lessons from cigarette advertising and attempts to control it in the United States from 1900 to 1965 with a selective, brief history of earlier tobacco use Paper presented at the Conference on Alternative Nicotine Delivery Systems, Toronto, March 1997.

8 Smith, C.J. et al. Human urine mutagenicity study comparing cigarettes which burn or pimarily heat cigarettes. Bowman Gray Technical Centre, RJ Reynolds Tobacco Company. Mutat-Res. 1996 Sep 26 ; 361(1); 1-9

9 Data provided by Roberta Ferrence, Senior Scientist, Ontario Tobacco Reduction Unit, Toronto, Ontario.

10 On October 18, 1994, the Patented Medicine Prices Review Board (PMPRB) obtained a 'voluntary compliance undertaking' from CIBA Geigy Canada Limited to offset excess revenues of $3.6 million, including a payment to the Government of Canada of $2.9 million. This is one of only three cases where the PMPRB has used its quasi-judicial powers/

11 Health Canada. Survey on Smoking in Canada, Cycle Three, Fact sheet No. 6. "Readiness to Quit Smoking – November 1994.