

Alternative Nicotine Delivery as a Harm-Reduction Strategy

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Tobacco use causes huge health, economic and social damage. In the United States and Canada alone, over 50 million people are spending over \$50 billion annually purchasing a product which will eventually kill 50% of its long term users. The vast majority of these users report that they would rather not be using tobacco and a significant percentage try to quit in any given year.

The principal reason tobacco products are able to cause such carnage is that these products contain, and are very effective delivery vehicles for, the addictive drug nicotine. Millions of people are addicted to this drug and use tobacco products as a way of satisfying this addiction.

To date virtually all efforts in tobacco control have been aimed at preventing the use of tobacco products, and, in so doing, breaking this nicotine addiction. Assuming we continue with past success rates in such endeavours (which is by no means certain) about 10 million further deaths in Canada and the United States will be attributable to tobacco products during the next 20 years alone. Worldwide, according to the World Health Organization, 500 million people currently alive will die from tobacco industry products - unless there are significant interventions.

There is a significant intervention available.

We can start by distinguishing between the drug and the delivery vehicle and develop policies accordingly. The health problems associated with nicotine dependency have little to do with the drug and very much to do with tobacco products as a very 'dirty' drug delivery device. It is the act of getting nicotine through the inhalation of smoke into the lungs which is responsible for vast numbers of deaths from cancer, emphysema and heart disease. While there is some evidence for nicotine itself being toxic, particularly with respect to the heart, this potential toxicity is certainly minor compared to the toxicity of tobacco products as a nicotine delivery vehicle.

The importance of dealing with nicotine dependence has already been demonstrated through the use of nicotine replacement therapy for those seeking to quit smoking. The use of nicotine containing products, such as gum and patches, can significantly increase the rate of smoking cessation. My concern is that these nicotine therapies have been directed at total cessation of both smoking and nicotine dependency. We have seemingly missed the fact that we can distinguish between these issues. The continued use of alternative nicotine delivery on a long term basis, as an alternative to tobacco products, would massively improve public health. Since the nicotine replacement therapies are short-term, many users are forced to return to tobacco products to satisfy a desire for nicotine. We are effectively condemning those with a continued need for nicotine to a deadly delivery system.

The problem of dirty drug delivery systems is not new. It is just that we do not de-construct the use of tobacco products to look at it in that way. The same distinction between drugs and delivery systems exists with IV drug users and dirty syringes. Many people talk of reducing the risks and harm associated with the use of these other drugs by the provision of cleaner delivery vehicles.

If we distinguish, in the case of tobacco products, between the drug and the delivery device we can

solve some major health problems. We could do this by allowing alternative, less hazardous, nicotine delivery devices on the market. This could be accomplished through legislative action that deals with "nicotine delivery" rather than just "tobacco". We can give consumers a choice, and manufacturers an incentive to compete for the nicotine market. Such legislation, like other areas of drug laws, would be predicated on maximum health benefit. In short, we can allow private enterprise to unleash its creativity in order to address our leading cause of preventable death.

Some of the advantages of such a system include:

- The use of alternative sources of nicotine could be seen as more than simply a cessation tool. Currently those who are strongly dependent on nicotine will go back to cigarettes after they have "failed" to break their nicotine addiction with patches, gum, etc. From a health standpoint the end of tobacco use is far more important than the continuing need for nicotine.
- Those who are truly dependent on nicotine will have an alternative. Today we are saying, in effect, "quit or die" to people who are unable to quit because of their addiction. This is akin to yelling at a stranded quadriplegic to run from a burning building.
- We clarify the morality arguments on tobacco control. Current arguments are based on such ideas as that it is 'wrong' to be using any drug and that anyone using nicotine can and should quit. The reality is that the health problem is immense, and clearly separable from the dependency concerns, and that a great many users find it virtually impossible to break their dependency. Hence, the chief moral concern should be to find the most effective ways of limiting this vast damage, and not the supposed weakness of character of the users. Clearly a failure by a society to take a known course of action which could prevent millions of unnecessary deaths raises greater moral questions than any 'weakness' on the part of those using the product.
- The ability of the alternative nicotine delivery system to make significant money for its purveyors (even a small portion of the tobacco market is potentially huge in terms of sales) would lead to better research and development of new products. This potential profitability could also allow for health-based restrictive measures on the marketing of these alternative nicotine delivery products without compromising their financial viability. These measures could include preventing sales to the unaddicted, determining where and how the alternative products may be marketed and any requirements with respect to assisting total cessation of nicotine use. By restricting the products on the market to those devices showing an overall improvement in the health situation we could ensure that new products really were improved products.
- The existence of alternative nicotine delivery could allow for greater societal protection from environmental tobacco smoke (ETS) since satisfying a nicotine addiction would no longer put at risk the health of others. The availability of alternative forms of nicotine delivery would answer the main argument that prevents a lot of environments from being smoke-free.
- The ability of these products to eliminate the current hazards of ETS would also mean that the demand for such products would be further enhanced by the interests of those in proximity to tobacco users. For instance, there could be strong pressure for a change in one's nicotine delivery vehicle from spouses, workmates, children or the operators of public places. The result will be a simultaneous acceleration in progress toward smoke-free spaces and the promotion of a more rapid reduction in tobacco use.
- The market for nicotine could be permitted in a way designed to favour the least harmful products. This could be done through regulatory constraints on promotion and use, pricing structure (via tax treatment) and by requiring changes to tobacco products which make them less efficient (and perhaps less palatable) nicotine delivery systems. For instance the taxes on tobacco would give a price advantage to alternative nicotine delivery and advertising restrictions on tobacco would give the alternative product a marketing advantage. Through further regulatory changes we could promote greater advantages for the least harmful nicotine delivery systems.
- We could create an important business whose financial wellbeing is dependent on going head-to-head with the tobacco industry. Unlike the present situation between tobacco

companies and health groups there would be much greater equality of resources. Currently the nicotine replacement therapies appear to have less than one percent of the North American nicotine market. Merely getting 10% of the total market (which is hardly ambitious) would create a powerful commercial counter-weight to the tobacco industry, particularly given the high profit margins that should be associated with such a business. Self-interest would dictate support for further efforts to control tobacco due to the resulting business advantage for the less harmful nicotine products.

- Politically this should not be too difficult. Most legislators support free enterprise and individual rights. Yet we have a situation where governments have inadvertently allowed monopolistic power over a drug to be placed in the hands of the tobacco industry and prevented consumers from freely exercising their ability to make choices about how to obtain that drug. Without regulatory change anyone seeking to market a product that people want, and which could save millions of lives and billions in economic costs, could be arrested rather than rewarded. The irony of this situation would not be lost on advocates of free-markets and believers in individual choice. The pressure for legislative change would be strong if the case was appropriately articulated.
- There are significant possibilities for action in the near term. In the United States the FDA is planning to regulate tobacco products and the topic is getting significant attention. In Canada the government is currently implementing a new, more comprehensive, approach to tobacco products that indicates a changing paradigm for tobacco control. If we could use this momentum for change to eventually put in place a regulatory regime for nicotine delivery, rather than just regulating tobacco products, we could allow for the intelligent development of alternative nicotine delivery.
- The first country to free the marketing of alternative nicotine delivery stands to create a huge local industry with great export potential. This will focus political support, and once a single country re-directs tobacco control policy in this way, others are bound to follow.

The histories of science and business are full of examples of where all that was necessary to cause a massive change existed for a long time before anything happened. The potential for change turns into actual change when people start looking at things in different ways. Millions of lives depend on us achieving such a paradigm shift on nicotine.

There are, of course, many possible problems with taking an alternative approach to dealing with nicotine addiction. But it is time for interested parties to sit down together to discuss the possibilities, the problems and the strategies. It is time to decide what is truly in the interest of world health and how we go about making any necessary changes to our current regulatory environments for tobacco and other nicotine products.

Just in the past year there have been significant developments in the delivery of nicotine which have the potential to herald a different approach to nicotine maintenance. There have been further disclosures of what tobacco companies have known about nicotine and addiction, R.J. Reynolds has introduced its Eclipse product in the United States, Germany (under the name Hi Q) and Sweden (under the name Inside), the OTC status of patches and gum has greatly changed that market, new pharmaceutical nicotine delivery products (known as "puffers" or "inhalers" have been introduced in Europe, and the FDA has concluded that cigarettes are drug delivery devices and decided to take action on these products.

There is a certain inevitability about changes to the nicotine market. The combination of better understanding of nicotine dependency, along with the advancing technology on its delivery and the massive potential market for less hazardous products will spur innovations. It is no longer a question of whether the nicotine market will change, but rather how it will change. If the health community is not active in seeking to direct this change it may be resigned to watching from the sidelines as health interests are subordinated to other concerns. An essential part of any analysis of an appropriate public health strategy on nicotine is to determine an appropriate regulatory regime for nicotine

delivery devices.

A 'NICOTINE MAINTENANCE MONOPOLY'

Though probably not intended, the result of government policies on nicotine products is to give the tobacco industry, and particularly the purveyors of its most harmful products, an effective monopoly over nicotine maintenance. The combination of regulations for nicotine delivering products results in a situation where only tobacco products can effectively provide the long term intake of nicotine upon which so many people are dependent. Potentially less harmful substitutes are prevented from entering the market due to constraints on "pharmaceuticals", and on any 'health claims' by tobacco companies.

As has been witnessed with monopolies in other areas of business, the result of this nicotine monopoly is that tobacco companies make exceptional profits, make decisions for political rather than economic reasons, stifle innovation and prevent inroads by alternative suppliers.

The tobacco industry as a 'nicotine maintenance monopoly' is most clearly demonstrated when seen in relation to the wide variety of alternatives for delivering nicotine. The newest generation of tobacco-based products (eg. Eclipse) and NRT products are probably the best known alternatives, but there are many more. A leaked Philip Morris "Competitive Analysis" document, reported on in the December 8, 1995 edition of *The Wall Street Journal*, lists nearly 100 patents for various forms of nicotine delivery.

There are clear market incentives for the development of products which can deliver nicotine without the health consequences of current tobacco products. Worldwide expenditures on tobacco products are somewhere in the range of USD\$300 billion. A product capturing even a small proportion of this market would generate massive revenue. Furthermore, various tobacco-specific excise taxes comprise a large proportion of the price of tobacco products, usually comprising at least half the retail price. With little basis to extend such taxes to many potential replacement products, the potential profit margin is very significant.

There are strong reasons to expect that a reasonable nicotine substitute could appeal to a large number of those currently using tobacco. A large percentage of all tobacco users wish not to be using these products but are dependent on nicotine. Even internal Imperial Tobacco Limited (ITL) documents (*The Canadian Tobacco Market at a Glance*, 1989) obtained during the constitutional challenge to the *Tobacco Products Control Act*, show that half of all smokers "intend" to quit and that over 40% make an attempt to quit in any given year.

The choice to quit using tobacco is, however, made difficult by a combination of social, psychological and physiological factors. Foremost among these appears to be the dependency on nicotine. The same ITL court document shows that the actual quitting rate averaged less than 2% a year from 1971 to 1989. Clearly, there is a tremendous unmet demand for consumers wanting to be free of tobacco but apparently unable to overcome this dependency. In the absence of an alternative, less deadly, form of nicotine delivery the success rates at quitting tobacco use will almost certainly continue to be sub-optimal and tobacco's death toll will mount.

If there were no other practical or less harmful way to administer nicotine the continuation of the nicotine maintenance monopoly could be acceptable. But there are other methods and many are appreciably less harmful. At the same time there appears to be rapid technological developments on potential alternative methods of delivering nicotine .

THE COSTS OF THE NICOTINE MAINTENANCE MONOPOLY

Looking at the tobacco industry as a nicotine maintenance monopoly, and seeing it in the light of the costs this monopoly imposes, helps identify the problems under the current regulatory environment. These costs are not only related to the harm from the use of tobacco products, but also the way the current systems of nicotine regulation aggravate this harm.

The health and economic costs of tobacco use are an obvious starting point in looking at the current nicotine-delivering products that are available. The World Health Organization has estimated that, in the absence of major interventions, 500 million people currently alive will die prematurely due to tobacco industry products. Half of all these deaths will occur, according to WHO, in middle age, and those people will lose an average of over 20 years of life. From any perspective this is clearly one of the most serious public health calamities to ever strike the human race.

The economic costs are similarly staggering. In a report prepared by a World Bank economist, it is conservatively estimated that tobacco use was a net drain on the world economy in 1990 in the range of USD\$200 billion. This is equivalent to the entire GDP of some OECD countries.

This level of harm is accentuated and maintained, albeit perhaps inadvertently, by our combination of regulatory systems for nicotine containing products. These include the following:

1) Differing Regulatory Regimes

Tobacco products have been exempted (in law or in practice) from the laws regulating drugs. This favourable treatment is not extended to the makers of NRT or the potential marketers of other nicotine-delivering products.

Tobacco products, where regulated, tend to be given tobacco-specific legislation and this legislation is universally weaker than the controls on other drugs. Drug laws are 'permissive' in nature; everything is banned unless it is permitted. As a result there are comprehensive controls over the import, manufacturing, distribution, promotion and sale of these products. Tobacco laws are generally 'restrictive' in nature; everything is allowed except that which is prohibited. Tobacco laws are a major fight for each restriction brought into being, and the lack of comprehensive authority allows legal 'loopholes' to be exploited for considerable lengths of time.

This difference in regulatory systems underpins the tobacco industry's position as a nicotine maintenance monopoly. It is essentially impossible for other products, under the existing regulatory regimes, to compete in any meaningful way with tobacco products. The power of this monopoly on nicotine maintenance then leads to other health harming and market distorting behaviour.

2) Promoting Image Rather than Product Attributes

With little to distinguish between the range of nicotine maintenance products available on the market the tobacco industry does not have to spend money competing with products with fundamentally different health impacts. The products which could provide competition based on health risks are either not on the market, or prevented from going head-to-head with traditional tobacco products. As a result the promotion of existing tobacco products is based on 'image' and none of the industry players have an incentive to give accurate information to consumers about the health implications of using any of the products.

3) The Stifling of Innovation

The tobacco industry has generally avoided innovative product re-development which could lower death tolls. It has little incentive to do so since there is no competition from outside the industry forcing it to adapt. This is the same as a national telephone monopoly having less incentive to

innovate than a telecommunications firm operating in a competitive market.

There have been some examples of tobacco industry looking at ways to reduce the hazards of its products. Usually, as has been seen with Jeffery Wigand at Brown & Williamson or Victor DeNoble at Philip Morris, this innovation is cut off. RJR and Swedish Tobacco may be exceptions to the general trend against innovation, but even with these companies the innovation is tentative and designed not to threaten the established tobacco market.

4) Tobacco Industry Consolidation

With no alternative products to contend with there is an incentive for tobacco companies to seek to dominate the permitted market in tobacco products. This allows for lower costs, and the extra price increases that enhance profits in the resulting less competitive market. The market consolidation is done through the purchase of other companies (as happens as new markets open up in such places as Eastern Europe) and the development of marketing plans built around product image rather than substance.

In virtually all tobacco markets in developed countries, the market is controlled by no more than two or three companies. This resulting domination by an oligopoly of the market for an addictive drug causes massive market distortions. Profits are usually both consistently, and extraordinarily, high. For the corporations involved this rewards (and bankrolls) any behaviour aimed at maintaining the status quo.

5) Decisions Based on Politics, Not Economics

Tobacco companies, like other monopolists, can succeed only with the support of governments. If competition is allowed to enter the marketplace, or the ability to exploit the monopoly's power is reduced through increased regulation, the results could be disastrous to these companies.

Tobacco companies seek political favours through obvious means such as the giving of money to politicians. These companies also make decisions on plant location, payments to suppliers, compensation for employees, sponsorships of cultural organizations, etc. in ways that often make little economic sense but great political sense. In Canada, for instance, the tobacco companies pay twice the market price for tobacco acquired from local farmers and pay well above market rates to workers in plants in Montreal.

These various costs of the nicotine maintenance monopoly means that we are not only facing massive unnecessary health tolls, but are allowing business decisions to be distorted and resources to be wasted. This would be a concern even if alternative products were merely theoretical.

In reality, though, there are various ways of delivering nicotine which are available now and could greatly reduce tobacco's toll. The failure to date to implement more pro-health policies has, to a large extent, been as a result of the legal framework that exists. A nicotine market operating under a different regulatory framework would be a different market. Allowing for differing forms of nicotine to be available for longer term nicotine maintenance would be an obvious way to open the market to a type of competition that could reduce the illness and economic losses associated with tobacco use. Free enterprise, rather than being seen as the cause of the tobacco epidemic, could be allowed to play a key role in the solution.

CHANGING THE NICOTINE MARKET

Any attempt at allowing alternative nicotine maintenance products on the market faces many obstacles. One of them is the realization that it is very unlikely to be a 'magic bullet', particularly in the

near future. The psychological and sociological associations of tobacco use and its long standing as a consumer product make a sudden and comprehensive switch to other products very unlikely. At most, some alternative products could be found to be acceptable to some current smokers who would otherwise not be able to cease using tobacco. As a result other aspects of a comprehensive plan to reduce tobacco use would continue to be necessary.

Changing the nicotine market in a way that allowed for less hazardous products to compete with standard tobacco products also raises questions about what sort of nicotine market should exist. Many questions need to be answered. For instance, is the use of nicotine something that would be acceptable even if the harm were minimized, or should we seek to eliminate nicotine use entirely? Does a safer alternative source of nicotine merely encourage smokers to continue smoking by fostering the belief that there is an alternative product available when it is needed? Do we add to the eventual disease toll by simply supplying those who would otherwise quit altogether? What are the issues involved with consumers using both tobacco products and an alternative nicotine source? Is the use of alternative nicotine for short term tobacco cessation (or to simply reduce daily cigarette use) a health gain or does it merely prevent overall cessation?

As difficult as all of these questions are, they are not new. The same sorts of issues have arisen with new tobacco products (low tar, etc.). But there has never been an appropriate way of measuring the potential health gains or losses and bringing forward appropriate policies to maximize the gains. Pharmaceutical policies do allow for (in fact, require) such an analysis but tobacco laws have had no such power.

DO WE NEED REGULATION?

It is possible to argue that the free market should be left to solve the problem. Anyone could put any product on the market and it would be up to the workings of the market to dictate which products would be successful. Such a system could get a lot of comparative information to consumers and they could be allowed to fend for themselves. Given the problems currently faced with tobacco use, and its monopoly over nicotine maintenance, a more open market might be considerably better than the status quo.

There are, however, strong reasons for some form of comprehensive regulation of all nicotine delivering devices. While there are strong philosophical arguments concerning government regulation of dangerous and addictive products, we need not look beyond the purely pragmatic.

The potential purveyors of alternative nicotine products will not want an unregulated environment, as most of them are satisfied with the overall direction of the regulation of pharmaceuticals. An entirely open market would actually be likely to put innovative products at a comparative disadvantage compared to the massive lifestyle-oriented campaigns of traditional cigarettes. Further, the governments currently regulating drugs and consumer products do so for a wide number of logical reasons and are unlikely to abdicate these responsibilities. There is virtually no chance of putting an addictive drug on the market, one that has played a key role in the massive death toll from tobacco use, and not have it regulated in some way. Since regulation is inevitable, the question is therefore one of the most appropriate form of regulation in order to achieve the maximum level of health benefit.

HOW TO REGULATE

If we are to seek the greatest practical reduction in the harm currently associated with nicotine use we need to look at a few fundamental changes in the regulation of nicotine delivering products. To begin with, less harmful products should not be placed at a marketing disadvantage. Indeed, there needs to

be a competitive advantage given to these products.

The appropriate regulatory system must also seek to ensure that the potential for harm reduction is attained. That is, the nicotine maintenance market must be forced to achieve ever-greater harm reduction.

While any system would require a serious review of the issues, there are a few points which appear valuable to be included:

EXISTING REGULATION OF NICOTINE PRODUCTS

There is a history of regulating tobacco products, and the marketing of these products. To date this regulation has generally been exceptionally weak in light of the magnitude of the problems caused by these products. There are, however, strong indications that this is changing. There is increased legislative action directed at tobacco around the world, and these actions are increasing in severity and scope. In Canada the new Tobacco Act would give specific regulatory authority over tobacco products and the marketing of these products. In the United States this action is best illustrated by recent developments by the FDA, but is by no means limited to that body.

There is also a long history of much more stringent regulation of nicotine-based pharmaceuticals. At present pharmaceuticals are placed under tremendous constraints. Whereas tobacco companies can market new or changed nicotine delivery products with minimal constraints, pharmaceutical companies can only market their nicotine products after years of evaluation, necessary approvals, and with prescribed limits on the marketing of the products. The philosophy of nicotine replacement therapy (NRT) regulation, like that of tobacco regulation, is in a state of change which is some ways is the opposite of that experienced with tobacco. While the FDA in the U.S. and Health Departments in other countries are seeking greater regulation of tobacco products, they are simultaneously relaxing the level of regulation of NRT. New products are being allowed on to the market and fewer restrictions are being imposed on this marketing.

The regulatory environment is likely to come under increased pressure for change as further forms of nicotine delivery products enter the market. New products are still subject to vastly different levels of regulation depending on whether they are classified as 'tobacco' or 'pharmaceutical' products. As the distinction between these categories becomes less stark this distinction will be harder to maintain. Further, the current inverse relationship between potential for harm and the level of regulation is likely to be seen ever less acceptable.

Without an appropriate form of regulation, new products and/or changes in existing products, may not be viable or might not meet public health goals.

They might simply be prevented from getting on the market or could be placed under too onerous a regulatory burden. At the same time it is possible that potentially harm-reducing products could end up being marketed in ways that do not actually achieve harm reduction.

THE FUTURE OF NICOTINE REGULATION

There is a substantial body of evidence indicating that some forms of nicotine delivery are significantly less harmful than others. Even among tobacco products there are differences in health impact. When tobacco products in general, and current cigarettes in particular, are compared to other forms of nicotine delivery (NRT, for example) the difference in health impact is immense. Given this situation it becomes important to consider how we could effectively regulate nicotine products in order to achieve

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