

Canada's Tobacco Package Label or Warning System: "Telling the Truth" about Tobacco Product Risks

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The Need for an Effective Package-Based Label System

The World Health Organization's draft Framework Convention on Tobacco Control (FCTC) will be presented to the World Health Assembly in May 2003. Its call for dramatically improved tobacco warnings worldwide reflects growing interest in tobacco package labelling or warning systems (1). This interest is augmented by greatly improved warnings now appearing on the shelves of retail outlets throughout the European Union, and by the announcements of other countries, such as Malaysia, of the planned introduction of reforms modelled on the Canadian or Brazilian warnings.

This heightened interest created by the FCTC process, and the encouragement it provides to parties to the Convention to implement more effective warnings, raises significant questions. Why are bigger and bolder warnings better? What messages are most effective? What tactics might be expected from an industry determined to undermine any measure that might cut its sales?

Canada has been one of the pioneering countries in developing and implementing innovative labelling requirements for tobacco products. This Country Report on warnings has been prepared in the hope that it will make a timely contribution to the development of similar reforms in other countries. Though some aspects of Canadian warnings are now well known, particularly the use of images, the debate and analysis that led Canada to move ahead in this area are less well understood. The gradual move towards large, explicit and graphic health messages came about because of a deepening understanding of the misinformation and deception that underlie the tobacco epidemic.

The right to be warned

The tobacco epidemic has rightly been described as a global catastrophe of unparalleled proportions: unless extraordinary public health interventions occur, tobacco products will kill 500 million people *among those alive at present*. (2) In other words, a single product category will kill about ten times the number of civilian and military casualties from the Second World War, even if future generations reject tobacco industry products.¹

In the Canadian context, about 45 000 smokers die annually from the tobacco epidemic.(3) In fact, Health Canada, which is the federal health department, estimates that the products of tobacco manufacturers will cause the

premature death of 3 million Canadians from among this country's 32 million population.(4) Such predictions of enhanced mortality of this magnitude necessitate extraordinary public health interventions.

In the case of major epidemics caused by viruses or bacteria, governments have a duty to provide clear, full information to their citizens on the seriousness of the diseases and how to avoid them; this general duty applies equally to tobacco. However, tobacco is unique among major epidemics in possessing its own public relations department, the tobacco industry, which has a vested interest in ensuring that consumers know as little as possible about the disastrous health effects of addiction to tobacco products.

Though the details of consumer protection law vary widely from country to country, there is widespread agreement on general principles, as exemplified by the *United Nations' Guidelines for Consumer Protection*. These guidelines recognize the right of consumers (a) to be protected from health and safety hazards in the marketplace and (b) to be given "adequate information to enable them to make informed choices" – including choices about risk.(5)

Historically, the marketing of tobacco products has grossly violated both of these principles. Consumers have been exposed to extremely large risks: mortality rates of 50 per cent for long-term users of tobacco.(6) They have not been provided with accurate information.

In Canada, tobacco manufacturers have had a longstanding duty at common law to warn their customers of the risks associated with their products. This duty requires tobacco companies to warn of both the nature of the risks (e.g. over 20 debilitating or terminal diseases alone (7)) and the magnitude of the danger (e.g. about 85 per cent of the time, lung cancer causes death, usually within two years (8)). The Ontario Court of Appeal, described the duty of all manufacturers to warn as follows:

Once a duty to warn is recognized, it is manifest that the warning must be adequate. It should be communicated clearly and understandably in a manner calculated to inform the user of the nature of the risk and the extent of the danger; it should be in terms commensurate with the

¹ World War II. Encyclopaedia Britannica 2003. Encyclopaedia Britannica Premium Service, Accessed 23 April 2003. <http://www.britannica.com/eb/article?eu=118868>



gravity of the potential hazard, and it should not be neutralized or negated by collateral efforts on the part of the manufacturer. (9)

Warnings of the nature and magnitude of risks are two clear responsibilities in Canada's consumer law. A third important principle of consumer protection is that the duty to warn may take different forms depending on the buyers (or prospective buyers). For example, in the case of a product designed for use by blind people, a manufacturer would have difficulty escaping liability for product hazards by pointing to a written warning included on the product.

More generally, consumer protection law makes special efforts to protect various types of *vulnerable groups*. Children are particularly vulnerable to deception or exaggerated advertising claims and usually cannot legally enter into major contracts, because they are deemed unable to judge reliably what is in their best interests. As well, people who are afflicted with terminal diseases are particularly vulnerable to advertising for "miracle cures".

Tobacco marketing is largely directed towards two such vulnerable groups: children/teenagers (who must be enticed to take up smoking if the industry is to replace customers who die or quit), and addicted adults. In the case of teenagers, the vulnerability is obvious: with good reason, society does not expect them to be able to make an informed choice between the promise of immediate if symbolic rewards (i.e. social acceptance and identity) and the prospect of dire consequences in a few decades' time (i.e. death in middle age). Nor is it realistic to expect dry, scientific information to compete with the emotional impact of well-crafted imagery.

In the case of addicted smokers, the vulnerability to misinformation comes from the phenomenon of cognitive dissonance: it is very difficult to go on believing one thing while doing the opposite. Specifically, for a smoker who is physiologically unable to refrain from smoking his or her next cigarette, there is a strong tendency to discount information about health risks – and to fall for pseudo-arguments typically provided by the tobacco industry. ("It hasn't been proven that smoking causes cancer" and "Tobacco is addictive in the sense that drinking soda pop is addictive", etc.).

The need to cut through cognitive dissonance, and to communicate effectively with children and teenagers, helps explain why Canadian tobacco-control policy has moved from occasional education campaigns, via print-only information on packages, to the present system of large, graphic-based warnings. Further, to help reduce cognitive dissonance, the new health information system includes help for smokers wanting to quit: clearly, it is easier to absorb health information if there is some hope that you can do something about your addiction.

The debate over warnings goes back almost three decades in Canada. The fact that the industry negotiated a weak, on the face of it absurd voluntary warning which was in effect from 1975 to 1988 ("The Department of National Health and Welfare advises that danger to health increases with amount smoked. Avoid inhaling") does not negate the industry's tort or civil law obligations during this period. Clearly, a voluntary agreement does not cancel the longstanding obligations that the industry has to its customers in civil law. Nor does Canada's new warning system give the industry complete sanctuary if current Canadian warnings are found to be inadequate. Section 16 of Canada's *Tobacco Act*² under which current warnings are mandated says:

This part does not affect any obligation of a manufacturer or retailer at [civil] law or under an Act of Parliament or of a provincial legislature to warn consumers of the health hazards and health effects arising from the use of tobacco products or from their emissions.

This section of Canada's tobacco statute preserves the civil law duty to warn, which could be more onerous than the duty spelled out in the new warning regulations. This section was in part a reaction to the tobacco industry's often successful use of federal labelling legislation in the United States of America as an argument to escape liability in that country's courts ("The Congressional Shield"). The United States courts have ruled that American warnings legislated by Congress protect the manufacturers from the responsibility of providing more meaningful warnings than those presently in use. It has been successfully argued that if Congress had wanted stronger warnings, Congress would have mandated stronger warnings.

Thus, regardless of the perceived strength of the Canadian warnings now, tobacco manufacturers long had a civil law duty to warn – which they ignored. Judge André Denis decided in 2002 to throw out the tobacco

² Available on-line at <http://laws.justice.gc.ca/en/T-11.5/index.html> .



industry's constitutional challenge to the *Tobacco Act* and Canada's landmark tobacco package warning system. Using remarkably strong language rebuking the manufacturers, he observed:

The duty [to warn effectively] must be imposed because the tobacco companies have continuously failed to fulfil their obligations in this respect [in civil law], despite their knowledge of tobacco dangers...The industry knew this [tobacco's harms], but said nothing."⁽¹⁰⁾

So it was, in the face of this decades-long failure to warn adequately, that the government forced the industry to implement Canada's first generation of world precedent-setting tobacco warnings in 1994.

Increasing Information about Tobacco Risks and the Elimination of Deception

Tobacco products are extraordinary in a number of respects. One of them is the unique nature of the product in terms of risk. Tobacco is addictive to children and has no safe level of use. Tobacco products kill on an extraordinary scale, causing the death of nearly one out of two of their long-term users.⁽¹¹⁾ Despite this, governments have allowed such products to be marketed in some of the most sophisticated and alluring packaging or trade dress ever developed. The message to users and to potential child and adolescent starters sent via the design and graphics of the package has been that the product inside is normal, legitimate and safe.

An effective package-based label and warning system can do much to counter the implicit reassurance provided by alluring packaging. In fact, because of the perfect targeting for these labels, the immense size of the target audience (in Canada, 5 million smokers, and their families) and the low cost of the measure, such a warning system has the potential to become the most cost-effective public health education campaign the country has ever seen.

There are at least two purposes of warning labels. First, as stated above, any warning system must inform potential and actual users of both the nature of tobacco risks and the magnitude of those harms, including the prognosis should a given tobacco-related disease strike.

The second purpose is less well understood than the first. Any effective warning system or package reform generally should also remove any deception that is part of the

package, including the deception related to the marketing of the family of low tar cigarettes, the 'light' and 'mild' consumer fraud. ^(12, 13) However, to the extent that any remaining colour and design on Canadian tobacco packaging suggests that the product is safer than it is or undermines the warnings of risk, that deception should also be removed. This objective will probably move health policy inexorably towards plain packaging (see text below).

Ancillary benefit to an effective warning system

Although some governments have taken steps to reduce tobacco advertising and promotion, most have ignored the lynch-pin of tobacco marketing, the package itself. All tobacco advertising, sponsorship and point-of-purchase promotion relates ultimately to the colour and graphics or trade dress of the package, like spokes are connected to the hub of a wheel. However important the packaging has been to the industry to date, as advertising bans increasingly take effect, the manufacturers will focus even greater attention on the package itself.⁽¹⁴⁾

In Canada, there are 2 thousand million packs sold annually, each one a miniature ad display. Each time a package is pulled from a pocket or purse, about 20 times a day for the average smoker, it creates an advertising impression. Tobacco packages place about 40 billion ad impressions into the Canadian market every year, a total that undoubtedly dwarfs the value of other tobacco promotions and advertisements. It is a legitimate health goal for governments to use large warnings to draw attention to the messages and to increase knowledge of risks. If the size of such messages coincidentally reduces the industry's ability to use the remainder of the package for the deception that is implicit in the alluring packaging, public health will benefit again. Even if governments, for any reason, feel they cannot use large warnings solely to diminish the promotional power of tobacco trademarks or package trade dress, they should be aware that, at a minimum, the reduction of this power is an ancillary health benefit.

The value of reducing the trademark's promotional power was acknowledged by the Quebec Court in its decision. Judge Denis wrote:

Warnings are effective and undermine tobacco companies' efforts to use cigarette packages as badges associated with a lifestyle [i.e. an adolescent badge suggesting entry into adulthood].⁽¹⁵⁾



Levels of Awareness of Tobacco Risks

Despite recent claims by tobacco manufacturers that their industry is now climbing to new heights of social responsibility, much offensive behaviour continues as before. For example, in the Rothmans 2002 Annual Report ³, Rothmans Benson and Hedges says:

RBH acknowledges the health risks which have been associated with smoking. The choice to smoke is made with full awareness of these risks which have been widely known for decades. (emphasis added)

By claiming that its products are only “associated with” disease, the manufacturer maintains the fiction that it has not been proven that the tobacco/disease relationship is a causal one. In fact, research reveals precisely the opposite of what this passage asserts.

The literature shows that many smokers, including child and adolescent starters, are generally aware that tobacco industry products are “bad for you”. But scratch below this superficial level of awareness and you will find a knowledge level that is clearly inadequate for such a lethal product.(16)

The World Bank addresses the level-of-awareness issue:

An overview of the research literature recently concluded that smokers in high-income countries are generally aware of their increased risks of disease, but that they judge the size of these risks to be smaller and less well-established than do non-smokers. Moreover, even where individuals have a reasonably accurate perception of the health risks faced by smokers as a group, they minimize the personal relevance of this information, believing other smokers’ risks to be greater than their own.

³ Available on-line at http://www.rothmansinc.ca/English/2002/Annual_Report/RINC.02.Colour.Eng.pdf.

⁴ NSRA calculation from Statistics Canada data on domestic sales of cigarettes and roll-your-own tobacco, and on population 18 years and over.

⁵ Joy de Beyer, World Bank, presentation to the International Conference on Illicit Trade, New York, July/August 2002.

Finally, there is evidence from various countries that some smokers may have a distorted perception of the health risks of smoking compared with other health risks.” (emphasis in original)(17)

It was in the absence of acceptable levels of awareness among starters and users that Canada implemented serious tobacco warnings reform in 1994.

The Context for Warnings

In the early 1980s, Canada had the highest rate of per capita tobacco consumption in the world.(18) However, in the decade following 1983, the country experienced rapid decline in per capita consumption, including a 34 per cent drop in the seven years to 1990.⁴ The fall in teen smoking rates was particularly dramatic, with prevalence rates virtually halved between 1981 and 1992.(19)

A number of factors contributed to this reduction, including the national debates over and enactment of two landmark tobacco control bills, the Tobacco Products Control Act (TPCA) and the Non-smokers’ Health Act (NsHA) in 1988, and the passage of municipal by-laws to regulate smoking in public areas and workplaces. The TPCA banned tobacco advertising and sponsorship. (Unfortunately, a loophole in the law gave the manufacturers an opportunity to continue sponsorships to date. The loophole is set to expire in October 2003.) The NsHA effectively banned smoking in federally-regulated workplaces (about 9 per cent of all workplaces), including federal buildings, banks, air and rail transportation and Crown corporations.

These valuable legal reforms were preceded by aggressive tobacco control advocacy. Undoubtedly, both the public debate and the law reform that followed reduced consumption. However, the single most important factor in the declines in consumption was likely the equally steep increase in tobacco taxation at the national, provincial and territorial levels from 1983 to 1991. (20)

Unfortunately, much of the momentum and some of the health gains during this 10-year period were lost in 1994 when the federal government and several of the provinces made substantial cuts in tobacco taxes to combat smuggling promoted by the tobacco industry.⁵ (21, 22)

The “half-price cigarettes” that resulted in much of Canada were the first of two major setbacks that slowed the remarkable momentum in tobacco control which had been building. The second was the loss in 1995 of the TPCA when the Supreme Court of Canada ruled, 5



votes to 4, that this legislation was unconstitutional. The *Tobacco Act* which replaced the *TPCA* in 1997 is the cornerstone of the federal government's legislative response to the tobacco epidemic. This statute bans most advertising and gives the government extensive power to regulate the tobacco industry, including the labelling of tobacco products.

In late 2000, as the latest generation of Canada's landmark labels or warnings started to appear in the market, 24 per cent of Canadians aged 15 years or more reported smoking, and 20 per cent were daily smokers. Smoking prevalence was higher among men than women: 26 per cent as compared to 23 per cent. Smoking among teenagers aged 15–19 was 25 per cent.⁽²³⁾

A series of tobacco tax increases in 2001 and 2002 has made it difficult to tease out the specific impact of warnings on consumption. Per capita tobacco consumption in 2002 was down a whopping 8.1 per cent on 2001. It would defy common sense to conclude that the new warnings had no role in such a remarkable decline.⁶

Canadian Warnings: 1994 Generation

With the passage of the *TPCA* in June 1988, Health Canada planned strong tobacco warnings including a world precedent-setting warning of tobacco addiction. But in a secret meeting with senior bureaucrats, tobacco lobbyists negotiated away the addiction warning and other reforms that would have revolutionized tobacco warnings.⁽²⁴⁾ The result was a warning system which incoming health minister Perrin Beatty said was so artfully hidden in the package colours that the tobacco industry could have taught the Canadian military lessons in "camouflage." ⁽²⁵⁾

In an appropriate response, Mr Beatty announced the first generation of Canada's landmark warnings in 1990. Almost immediately, this reform stalled. The delay was caused by a risk-averse approach to implementation related to the tobacco industry's constitutional challenge of the *TPCA*. The Non-Smokers' Rights Association (NSRA), Canadian Cancer Society (CCS) and the Heart and Stroke Foundation of Canada then led a three-year campaign for enactment including a letter mailed to one million households in the constituencies of federal cabinet ministers.

The black and white, text-based warning system finally appeared on cigarette packages in 1994. The new warnings undoubtedly blunted, to some degree, the extremely negative effects of the almost half-price cigarettes available

in much of Canada following the tobacco tax reductions. Unfortunately, the appearance of the new warnings made it more difficult to measure the negative impact of the tax cuts independently of the positive gains from the improved warnings.

By world standards, the labels produced in 1994 were indeed impressive, setting global precedents for tobacco warning systems.⁽²⁶⁾ The warnings, excluding borders, were the largest in the world (25 per cent of principal display areas) and the first to appear on both major faces of the package: English text on one face and French on the reverse. The warnings *plus* borders occupied as much as 40 per cent of each major face of the package one entire side panel. Of considerable importance, these warnings were placed at the top of the major faces, the premier location on the package.

The tobacco industry was also forced by these warnings into a black-and-white format, which prevented the manufacturers from camouflaging the warnings in the package colours. Half of the time, the warnings were printed with black lettering on a white background with a 3 mm black border. For the other half, the law required the opposite: white lettering on a black background with a white border, the graphic format that the industry found the most distasteful.

There were other breakthroughs in the 1994 warning system. For the first time, a causal relationship between the product and disease was recognized in a tobacco warning ("Cigarettes cause cancer"). These warnings were the first to transfer the responsibility for the epidemic from individual behaviour (smoking) to the industry's products ("Cigarettes cause cancer"), the first to warn of addiction ("Cigarettes are addictive"), the first to establish environmental tobacco smoke as the cause of terminal disease ("Tobacco smoke causes fatal lung disease in non-smokers"). Given the notable departure from the largely invisible warnings that preceded them, these dramatic warnings shocked the country when they first appeared.

The focus on tobacco packages did not end with these changes. When tobacco taxes were cut in 1994 in order to price smugglers out of business, the House of Commons health committee was asked to review the sale of tobacco

⁶ Comparing 2002 (Jan–Dec) with 2001, per capita consumption of cigarettes plus roll-your-own (assuming 0.7g of ryo = 1 cig) was down 8.1%.



in plain packages. (Plain packaging is defined as packaging on which the surface graphics currently used to differentiate brands have been standardized.(27) Plain packs incorporate a standard package base colour and are stripped of any trademark colour, graphics and language.) Early in 1995, the committee recommended plain packaging (28) but tobacco lobbyists worked hard to stall this reform. A focused advocacy campaign would be required to force the implementation of this recommendation.

Canadian Warnings: 2000 Generation

Enactment and implementation

The latest iteration of Canada's warnings was implemented by the then health minister Allan Rock under Section 15 of the *Tobacco Act* and implemented by way of regulation in June 2000. The law required that about 50 per cent of tobacco packages had to have the new warnings in place within 6 months from enactment. Any remaining packaging had to comply within 1 year. This gave the industry some flexibility related to problems of production and clearance of inventory. The regulation dictated the labelling of tobacco products sold in individual packages, cartons and tubs, and applies to products produced domestically and imported.

Two distinct warning systems

Canadian cigarette packages consist of three types. The most common package in Canada – though it is virtually unknown elsewhere – is the shell and slide design which accounts for over 85 per cent of the Canadian market. The slide surrounding the cigarettes moves up and down inside the outer shell on which most of a company's trade dress is printed. The package with about 10 per cent of the market is a flip-top box, common in other markets. Soft packs, the third type of pack used, account for less than 1 per cent of sales.

There are two distinct warning systems in the new Canadian labels for manufactured cigarettes: (a) an exterior system printed on the shell of the most common package and on the outside of the flip-top box or soft pack; (b) an interior system printed on the slide or on a leaflet which is inserted inside the flip-top package. As explained below, some tobacco products that occupy a small segment of the market face less stringent requirements. For example, a loophole given to manufacturers exempts soft packs from the leafletting requirement imposed on flip-top boxes.

This could encourage manufacturers to shift production to

soft packs to avoid carrying the interior warning/cessation system.

Exterior warnings

The regulation requires 16 warning labels in rotation which use full colour, pictures and graphics⁷. These labels occupy the upper 50 per cent of both of the "principal display surfaces" of each package: English on one side, French on the other (Canada's two official languages). These are the warnings that have captured international attention.

Considerable focus-group testing and polling went into determining both the size and the format of the exterior warnings. Smokers consistently reported that warnings with images were far more likely to influence their behaviour, and that of youths who might be tempted to start smoking. They also reported that larger warnings would be more effective in encouraging them to quit. Initially, the government announced warnings that would occupy 60 per cent of both major faces. Subsequent research suggested that warnings of 80 per cent would be even more effective.(29) Despite this, in the trade-off that normally accompanies political decisions of this kind, the health minister settled for warnings occupying the upper 50 per cent of both major faces. These measures set global precedents in both size and content.

Interior warnings

Health Canada made only a modest effort to realize the potential of the interior system. It consists of 16 messages in rotation printed on either the slide of the dominant package type, or on a removable insert for the flip-top box. When the interior system was originally recommended to Health Canada by health groups, it was suggested that any messages rotated on the inside should be a "surprise" to the smoker, which would only be revealed after the purchase was made. Because of this feature, the impact of the interior messages would only be limited by the obvious requirement of scientific and legal validity and the skills of the advertising creative team.

Considering Health Canada was breaking new ground with these warnings, and that the *Tobacco Act* under which the warnings were being implemented was under

⁷ See "Images of Canadian Health Warnings," at http://www.nsr-a-dnf.ca/news_info.php?cPath=22&news_id=78



attack in the courts, the development of the interior system proceeded with some timidity. These restraining influences caused the interior messages to be limited to high-lighted text without full colour, pictures or graphics.

Whatever the limitations of the interior system in this generation of warnings, the government did establish the precedent of using the inside of the pack. This gave Health Canada the potential to develop this system more fully in the future.

Messaging

Tobacco industry documents reveal concern about effective warnings. One British American Tobacco (BAT) document says, "There should be no specific mention of smoking related disease" in warnings. (30) Another says, "Reference to specific diseases on health warnings should be resisted strongly." (31) Industry objections notwithstanding, the exterior warnings speak to specific risks: addiction, lung cancer (two messages), heart disease, emphysema, mouth disease, stroke, second-hand smoke (three messages), maternal smoking during pregnancy (two messages), effect of parents' smoking on the risk of uptake among children, a warning of hydrogen cyanide, and a "proportionality" message (deaths from tobacco compared with other causes of preventable death).

The 16 interior messages include the following: nine positive messages to encourage cessation (beginning "You CAN quit smoking!") and seven more detailed messages to complement the exterior warnings introduced by questions such as:

- "If I get lung cancer, what are my chances of surviving?"
- "Can second-hand smoke harm my family?"
- "Can tobacco cause brain injury?"

To ensure print quality control, the regulation specifies that the "warnings and health information" must be obtained from electronic images obtained from Health Canada and that the quality must be "as close as possible to the colour" set out in Health Canada's source document.

The toxic constituent panel

In addition to the package faces occupied by the warning systems described above, one side panel of each package carries information about machine-measured yields of various smoke constituents. In the warnings introduced in 1994, yields of three toxins were listed: tar, carbon

monoxide and nicotine, as measured by machine using International Organization for Standardization (ISO) testing parameters.

It was by then well established that ISO numbers do not provide meaningful information on quantities of toxins absorbed by smokers – a 'light' cigarette can easily give the same amount of tar as a 'regular' one, as smokers adjust puff volume and other characteristics to achieve their habitual nicotine dose. The government had developed a new set of testing parameters, designed to approximate yields under realistic conditions of smoker compensation.

The decision was made that the new 2000 format would include a range that would show the yields of both the ISO and "realistic" parameters. While this approach makes it less easy to tie misleading marketing devices, such as the 'lights' moniker, to officially sanctioned tar yield numbers, it is still far from satisfactory.

The range between the results from the two test methods is considerable, particularly in the case of highly ventilated cigarettes⁸. To the extent that smokers optimistically believe their personal exposure level to be near the lower end of the range, they may assume a health benefit to brand-switching where actually none exists.⁹

Canadian health organizations recommended that the ISO numbers be dropped altogether. However, Health Canada was reluctant to abandon the ISO system completely, which the government had embraced for many years. Nevertheless, health groups expect changes in the next generation of warnings. In the meantime, Health Canada has added three new toxins in tobacco smoke that the

⁸ See "Toxic constituents information" at http://www.nsr-adnf.ca/news_info.php?cPath=22&news_id=187 .

⁹ For example, in the popular brand family Player's, Player's Filter (i.e. regular) has a tar rating of 15-33 mg. Player's Extra Light has a rating of 11-29 mg. The newly introduced Player's Silver has a range of 8-27 mg. Somebody switching from regular to Silver would quite naturally assume that in the process they reduced their exposure substantially, possibly by as much as 50% (from 15 to 8 mg, say). In fact, they are likely at the lower end of the range when they smoke the regular and at the higher end when they smoke the Silver, e.g., 20 mg in either case.



industry must now report in the toxic constituent panel: benzene, hydrogen cyanide and formaldehyde.

Health Minister Rock published a *Notice of Intent to Regulate* in 2001 to signal the intent to ban 'light' and 'mild' descriptors. However, to date, with a change in ministers, this reform seems stalled.

Pipe tobacco and cigars

These tobacco products occupy a very minor part of the Canadian market and have less stringent warning requirements to meet. Manufacturers must rotate four bilingual warnings with pictures, colour and graphics. Bidis, chewing tobacco, oral snuff and nasal snuff carry four text-only messages in rotation.

Cartons and kits

Each carton must carry one of 16 warnings in rotation which occupy 50 per cent of the surface area of every face. This requires each carton to have three warnings in English and three in French chosen from among the 16 exterior warnings required on individual packages. Because every face of the package has a warning, the manufacturers and retailers are prevented from stacking cartons in such a way as to create a large, warnings-free cigarette display at point-of-purchase.

Marker words

A typical feature of warning labels and signs is the use of marker words such as "CAUTION", "WARNING", or "DANGER". Almost all of Health Canada's messages utilize "WARNING" or "AVERTISSEMENT". The marker word "CAUTION" is not strong enough for a product that kills and has no safe level of use. "DANGER" suggests that the hazard or risk is immediate or imminent; this marker was therefore thought to be inappropriate. Markers are often highlighted in some way. Graphically, it was thought that "WARNING" or "AVERTISSEMENT" in red or yellow was most effective depending upon the background colour. For example, red markers disappear on black backgrounds in some Canadian warnings. Yellow should have been used.

Attribution and extraneous messaging

Health Canada rejected the language encouraged by the industry, whereby the authority to which the warning is attributed leads the message; for example, "Surgeon General's Warning: Smoking causes..." or "The Department of National Health and Welfare advises..."

This ordering of the language forms a word block and allows the dissonant smoker to ignore the rest of the warning. Therefore, the attribution to "Health Canada" in small typeface was wisely placed below the warning.

To Health Canada's credit, it also rejected an attempt by the tobacco industry to slip in the following message "Underage sale prohibited." The government recognized that industry attempts to position its products as "for adults only" encourages youth to attempt to use cigarettes as a "badge" signifying entry to adulthood.

Wear-out

Warning labels become stale with the passage of time. To address problems related to obsolescence or "wear-out", at the time of enactment of the 2000 generation of warnings, the government committed to changing and refreshing the warnings within three years.

Success of the Intervention

The purpose of the intervention was to provide current and potential smokers with accurate information, compellingly presented, with respect to the nature and magnitude of the risks of tobacco products. In the face of the continuing tobacco epidemic, the government sought to address at least partially the manufacturers' ongoing failure to provide full and accurate risk information. Clearly, it will take many years before the effects of decades of omission and misrepresentation are overcome; but access to proper warnings is a public benefit in itself.

The short-term impact of the warnings on consumption or smoking rates is impossible to quantify, because of a number of other tobacco control measures, such as tax increases, workplace smoking bans and mass media campaigns that were implemented virtually simultaneously. However, smokers and recent ex-smokers are surprisingly numerous in reporting that the new warnings were "a factor" or "a major factor" motivating a recent quit attempt.¹⁰

¹⁰ A total of 38%, according to a survey conducted in October 2001. See Environics Research Group, Evaluation of new warnings on cigarette packages (Research prepared for the Canadian Cancer Society). Available on-line at http://www.cancer.ca/vgn/images/portal/cit_776/35/20/41720738niw_labelstudy.pdf



What the research shows

In general terms, smokers are saying, "Give us the truth, however uncomfortable, anything that will help us get off cigarettes." (32) Quantitative and qualitative research completed both before and after enactment of Canada's new warnings shows that:

- smokers and potential starters have an imperfect understanding of the nature and magnitude of the risks of tobacco use (33);
- large warnings with pictures and graphics in colour are seen as crucial, first, in attracting attention to messages (34) and, second, in increasing the desire to quit smoking (35);
- emotive messages are often more effective than statistics (36);
- personalized messages are more effective than impersonal ones (37);
- messages about risks which have a component involving personal appearance have a greater impact (e.g. Canada's warning about mouth disease) (38);
- positive messages related to cessation assistance in conjunction with strong risk messages are more effective (39). Not unexpectedly, if anxiety about risk is raised, suggestions that offer hope of avoiding the risk are warmly received;
- after a few months on the market, package warnings had high visibility and were rated a "top-of-mind" source for health information. (40)

The Quebec Superior Court reviewed the evidence about the efficacy of the warnings and concluded the "warnings are effective." Judge Denis said:

A study commissioned by Rothmans, Benson & Hedges Ltd. (R.B.H.) in the year 2000 (Project Jagger, June 23, 2000) mentioned in Dr. Pollay's report shows that the warnings with photos recently mandated by the federal government are having a *major impact on consumers.*" (emphasis added) (41)

Attempts to Block Labelling Reform

Opposition to the labelling reform came from three principal sources: the three major Canadian manufacturers, the Canadian Tobacco Manufacturers' Council, and tobacco package printers who were either incited or frightened by their manufacturer clients. This followed a plan outlined in

a secret presentation given to directors and advisors of the Canadian Tobacco Manufacturers' Council in 1999. One goal of the plan was "to stall and, ultimately, significantly amend government's proposed regulations on packaging and point-of-sale." The document makes clear the need to organize unions in opposition and to "coordinate anti-packaging campaign with key suppliers." (42)

A variety of arguments were employed. It is worth underlining that the content of the warnings was not at issue. The manufacturers said they would not contest the language, presumably because they could not win such a protest. Attempts to block the reform focused on:

- the constitutionality of taking 50 per cent of the package's trade dress, an alleged infringement of the industry's commercial freedom of speech,
- the claimed inability of the printers, using a rotogravure printing process, to meet the requirements of Health Canada to produce both full colour warnings and the sophisticated printing demands related to industry trademarks, and
- the threatened loss of jobs when printing contracts moved to the United States.

However, unlike in the plain package debate, alleged violations of international trade laws and of intellectual property rules did not feature prominently in the political fight over the warnings.

Pressuring the government to proceed and countering the various industry blocks was a coalition of over a 100 national and regional health and human service organizations led by the NSRA and the CCS.

Threats related to constitutional issues were countered by lawyers acting for the federal Attorney General and the CCS. To counter the block created by the printers and their clients, the health organizations enlisted the aid of printing experts. Health Canada showed leadership by manufacturing cigarette packages which proved that the warnings could be produced while protecting the manufacturers' trademark colours.

Curiously, as soon as the warnings were approved by parliament, the issue of job losses disappeared into the ether. The manufacturers did follow through with their legal assault on the warnings. This argument was rolled into the constitutional challenge of Canada's *Tobacco Act* then underway. In December, Judge Denis said the rights of the industry under the Charter "cannot be given the same



legitimacy as the government's duty to protect public health" and rejected all of the industry's challenges.⁽⁴³⁾

Factors Leading to Enactment in 2000

In the real world of tobacco control, many factors influence the formation of policy and the final form of interventions. In an observation attributed to Bismarck, it is said that there are two things one might not wish to see in production: sausages and laws. Several factors impacted on the development of the Canadian warnings and not all of them were health based. Prior to the announcement of health minister Rock's plans for new warnings, his government had been severely criticized for concessions given on tobacco sponsorship to international motor-racing. Although the minister had little to do with the concessions, he was an activist minister and wanted to make a positive contribution to the development of the tobacco file. After receiving a thorough briefing on the importance of tobacco warnings and the role of the package in tobacco marketing by a non-governmental health agency, he decided in 1999 to proceed with improvements to the package warning system.

The NSRA, CCS and Physicians for a Smoke-Free Canada led non-governmental organization (NGO) advocacy for the 2000 warnings reform. In particular, the NSRA manufactured a prototype warning system⁽⁴⁴⁾ and the CCS contributed valuable research on a variety of issues related to the new warnings. Health Canada conducted its own research including research on recommendations originating with the NGO community.

Because the changes being planned were substantial, time constraints soon became a factor. In the rush to completion, the final product was influenced by legislative time constraints, lack of optimal time for research and testing, risk averseness related to litigation, and uncertainty with respect to how intrusive the warnings could be. For example, the failure to commit to a complete interior warning system earlier in the process affected the quality of that system.

Despite these problems, the product that emerged in late 2000 was a precedent-setting system, a system that went further than any other tobacco labelling system in any country at the time. This success may in large part be attributed to factors not always acknowledged in the development of public policy and we stress their importance. There were three key influencers in the system working cooperatively and with commitment towards

the development of an outstanding system. First, we had a unified health community pressing for the initiative, developing a prototype of a breakthrough system,⁽⁴⁵⁾ conducting research⁽⁴⁶⁾ and generating counter pressure to the opposition from the tobacco industry. Second, there was a health minister and a key ministerial aide who were committed to the reform and who provided the political leadership so very essential for enactment. Third, there was a team within Health Canada charged with the responsibility to see this project to completion which worked hard and with commitment to move the warnings to completion. In the absence of leadership from any of these three interests, the new warnings may not have come to fruition.

Recommendations

Our experience with the warnings reform process suggests the following recommendations:

1. Select warnings that cover the nature of the risks and the magnitude of the danger. Warnings should provide information about specific diseases and the prognosis if a tobacco disease strikes.
2. Cessation information that offers hope works well when it follows anxiety-raising warnings. But cessation information should not overwhelm the purpose of the warning system expressed in point 1 above.
3. Risks of disease should be attributed to the product (e.g. cigarettes), not to individual behaviour (i.e. smoking). Cessation messages can focus on individual responsibility.
4. Non-smokers should not be overlooked as targets of any warning system. Second-hand smoke warnings are of great interest to them. Spouses, children and friends of non-smokers read the warnings and encourage smokers to quit.
5. Warnings should be large and utilize blunt language, pictures, colour and graphics.
6. Warnings should be introduced by an appropriate marker, such as WARNING.
7. Personalized messages work best, for example, "Cigarettes can kill you!"
8. Weasel words such as "is related to", "is linked to" or "is associated with" should be rejected to the extent that science permits. Identifying causation is important, for example, "Cigarettes can cause lung cancer, in you!"



9. Blocks in warnings created by difficult or wordy language should be avoided.
10. Position of warnings counts. The top of major package faces is the premier space on a package. This position sells cigarettes. Government should occupy it in the interests of public health.
11. Second-hand smoke (especially death from second-hand smoke diseases) and addiction are two warnings themes that cause the tobacco industry special discomfort.
12. In text-only warnings, white lettering on black background, is more dramatic than the reverse, especially if it is framed with a white border. Attempts to camouflage the text of messages in the colours of the package should be rejected.
13. Deception undermines warning systems. Deceptive claims or graphics should be banned (e.g. the 'light' and 'mild' family of descriptors).
14. Just as creativity with trademarks on packages is being used by the industry, creativity should also be utilized with warning systems (e.g. surprise messages inside the pack).
15. Warnings should be rotated frequently. Wear-out of messages should be prevented by scheduling regular changes to the warning system.
6. Doll R. et al. *Mortality in relation to smoking: 40 years' observation on male British doctors*. British Medical Journal, 1994, 309:901-11.
7. Health Canada. *Regulatory Impact Analysis Statement (Tobacco Products Information Regulations)*. Canada Gazette Part I, 1 April 2000, p961.
8. Health Canada. If I have lung cancer, what are my chances of surviving? Available on-line at <http://www.hc-sc.gc.ca/hecs-sesc/tobacco/facts/surviving/index.html>
9. Buchan V. *Ortho Pharmaceutical (Canada) Ltd*, Ontario Court of Appeal, 17 January 1986, 54 Ontario Reports (2d): 92-123.
10. JTI-MacDonald Inc. c. Procureure Générale du Canada (2002) C.S., p. 84, para. 473, p86, para484
11. Doll R. et al. *Mortality in relation to smoking: 40 years' observation on male British doctors*. British Medical Journal, 1994, 309:901-11.
12. Intergovernmental Negotiating Body on the WHO Framework Convention on Tobacco Control. *Draft WHO framework convention on tobacco control*. Geneva, World Health Organization, 3 March 2003, Article II, 1(a).
13. The 'light' and 'mild' consumer fraud. A brochure published by the Non-Smokers' Rights Association and Smoking and Health Action Foundation, December 2002, 8pp. Available on-line at <http://www.nsra-adnf.ca/DOCUMENTS/PDFs/LightMildbrochure.pdf>

References

1. Intergovernmental Negotiating Body on the WHO Framework Convention on Tobacco Control. *Draft WHO Framework Convention on Tobacco Control*. Geneva, World Health Organization, 3 March 2003.
2. Peto R, Lopez AD. "Future World-Wide Health Effects of Current Smoking Patterns". Critical Issues in Global Health (Koop E, Pearson CE, Schwarz MR, eds). San Francisco: Wiley, 2001.
3. Health Canada. *Regulatory Impact Analysis Statement (Tobacco Products Information Regulations)*. Canada Gazette Part I, 1 April 2000, p961.
4. *Tobacco control: a blueprint to protect the health of Canadians*. Health Canada, 1995, p16.
5. United Nations Conference on Trade and Development. *United Nations' guidelines for consumer protection*. Geneva, United Nations, 2001.
14. Slade J. *The pack as advertisement*. *Tobacco Control*, 1997, 6:169-70
15. JTI-MacDonald Inc. c. Procureure Générale du Canada (2002) C.S., p42.
16. US Centers for Disease Control and Prevention. A submission in response to Federal Trade Commission File No. 992-3025. Proposed consent agreement with RJ Reynolds regarding Winston "No Additives" cigarettes. Atlanta, GA, CDC, National Centre for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 1999, May 17: p2.
17. *Curbing the epidemic: governments and the economics of tobacco control*. Washington, The World Bank, 1999, p30.
18. Surveying the damage: cut-rate tobacco products and public health in the 1990s. Canadian Cancer Society, Non-Smokers' Rights Association, Physicians for a Smoke-Free Canada, Quebec Coalition for Tobacco Control, October 1999, p24.



- Available on-line at <http://www.nsr-a-dnf.ca/DOCUMENTS/PDFs/oct99taxrep.pdf>
19. *Surveying the damage: cut-rate tobacco products and public health in the 1990s*. Canadian Cancer Society, Non-Smokers' Rights Association, Physicians for a Smoke-Free Canada, Quebec Coalition for Tobacco Control, October 1999, p24.
 20. *Surveying the damage: cut-rate tobacco products and public health in the 1990s*. Canadian Cancer Society, Non-Smokers' Rights Association, Physicians for a Smoke-Free Canada, Quebec Coalition for Tobacco Control, October 1999, pp8, 24, 25.
 21. Stephens T. *Trends in the Prevalence of Smoking, 1991–1994*. Chronic Diseases in Canada. Health Canada, Vol 16, No. 1, Winter 1995.
 22. Media release of the Ontario Tobacco Research Unit, October 12, 1995 for *Monitoring Ontario's tobacco strategy, progress toward our goals*. Centre for Health Promotion, University of Toronto, October 1995.
 23. Health Canada. Canadian Tobacco use monitoring survey 2000. Supplementary tables. On-line at <http://www.hc-sc.gc.ca/hecs-sesc/tobacco/pdf/ctums/suptables2000.pdf>
 24. Graham Fraser. *Group says tobacco warnings weakened*. The Globe and Mail, 26 June 1988, p1.
 25. Canadian Press. *Warnings don't stand out*. The Ottawa Citizen, 31 May 1989, pA11
 26. Mahood G. *Canadian tobacco package warning system*. Tobacco Control, 1995, 4: 10–14.
 27. *When packages can't speak: possible impacts of plain and generic packaging of tobacco products*. Health Canada, March 1995, p1 (Expert Panel Report).
 28. *Toward zero consumption, generic packaging of tobacco products*. Ottawa, House of Commons, June 1994 (Report of the Standing Committee on Health).
 29. Environics Research Group Ltd. Reactions to cigarette packaging formats. Prepared for the Canadian Cancer Society, Focus Canada 1999-1 March 1999. Also Environics Research Group. Reactions to cigarette packaging warning message sizes. Prepared for the Canadian Cancer Society, Focus Canada 1999-3, 1999.
 30. Anon. *BAT Board guidelines, public affairs 1982*. Entered as plaintiff's exhibit 13866 in *State of Minnesota et al. v. Philip Morris, Inc., et al*. See Bates number 680585252. Document available on-line at http://www.tobacco.neu.edu/mn_trial/TE13866.pdf
 31. Anon. *BAT topics in smoking and health 'Bible', 1992*. Bates numbers 500887584-887709. Document produced in *State of Minnesota et al. v. Philip Morris, Inc., et al.* and included in the Minnesota Select Set of tobacco industry documents. Available on-line via <http://outside.cdc.gov:8080/BASIS/ncctld/web/mnimages/DDW?W=DETAILSID=74>
 32. Environics Research Group. Qualitative (focus group) report regarding health warning labels and images on cigarette packages – final report (Research prepared for Health Canada – Office of Tobacco Control), HC-003-155-9904, March 1999. Available on-line at <http://www.hc-sc.gc.ca/hecs-sesc/tobacco/pdf/warning.pdf>
 33. Environics Research Group. *Assessment of perceived health risks due to smoking* (Research prepared for Health Canada – Office of Tobacco Control), H4097-9-0025/001/CD, November 1999.
 34. Environics Research Group, Qualitative (focus group) report regarding health warning labels and images on cigarette packages – final report (Research prepared for Health Canada – Office of Tobacco Control), HC-003-155-9904, March 1999. Available on-line at <http://www.hc-sc.gc.ca/hecs-sesc/tobacco/pdf/warning.pdf>
 35. Environics Research Group. Qualitative (focus group) report regarding health warning labels and images on cigarette packages – final report (Research prepared for Health Canada – Office of Tobacco Control), HC-003-155-9904, March 1999. Available on-line at <http://www.hc-sc.gc.ca/hecs-sesc/tobacco/pdf/warning.pdf>
 36. Liefeld, JP. *The relative importance of the size, content and pictures on cigarette package warning message* (Research prepared for Health Canada – Office of Tobacco Control), September 1999. Available on-line at <http://www.hc-sc.gc.ca/hecs-sesc/tobacco/pdf/liefeld-eng.pdf>
 37. Anon. *BAT Board guidelines, public affairs 1982*. Entered as plaintiff's exhibit 13866 in *State of Minnesota et al. v. Philip Morris, Inc., et al*. See Bates number 680585252. Document available on-line at http://www.tobacco.neu.edu/mn_trial/TE13866.pdf
 38. Environics Research Group, Evaluation of new warnings on cigarette packages (Research prepared for the Canadian Cancer Society). October 2001. Available on-line at http://www.cancer.ca/vgn/images/portal/cit_776/35/20/41720738niw_labelstudy.pdf
 39. Strahan EJ et al. *Enhancing the effectiveness of message labels on tobacco packaging* (Technical report prepared for the Centre for Behavioural Research and Program Evaluation and the National Cancer Institute of Canada), March 1999.



40. Environics Research Group. *The health effects of tobacco and health warning messages on cigarette smokers – survey of adults and adult smokers – Wave 2 surveys* (Research prepared for Health Canada), PN4892, August 2001.
41. JTI-MacDonald Inc. c. Procureure Générale du Canada (2002) C.S., p40, para213.
42. Anon. Presentation to meeting of CTMC [Canadian Tobacco Manufacturers' Council] directors and advisors, Montréal, May 27, 1999. Document available on Philip Morris discovery documents website at Bates numbers 2072677493-7510: <http://legacy.library.ucsf.edu/tid/imh42c00>
43. JTI-MacDonald Inc. c. Procureure Générale du Canada (2002) C.S., p. 94, para. 536.
44. Mahood G. *Warnings that tell the truth: breaking new ground in Canada*. Tobacco Control, 1999, 8(4):356–361.
45. Mahood G. *Warnings that tell the truth: breaking new ground in Canada*, Tobacco Control, 1999, 8(4):356-361.
46. Environics Research Group. Evaluation of new warnings on cigarette packages (Research prepared for the Canadian Cancer Society). October 2001. Available on-line at http://www.cancer.ca/vgn/images/portal/cit_776/35/20/41720738niw_labelstudy.pdf

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