Tobacco package health warnings: a global success story

Rob Cunningham

Canadian Cancer Society,
Ottawa, Ontario, Canada

Correspondence to
Rob Cunningham, Canadian
Cancer Society, Ottawa, ON K1P
5G3, Canada;
Rob.Cunningham@cancer.ca

INTRODUCTION

Thirty years ago, in 1992, the largest cigarette package health warnings in the world had a size of just 20% of the package front and back. Those warnings, in Canada, were text-only messages in package colours that appeared at the bottom of the front and back surfaces. Over time, warnings have become much larger and the use of graphic pictures has become widespread (figures 1–4). The WHO Framework Convention on Tobacco Control (FCTC),¹ together with the FCTC implementation guidelines for packaging and labelling,² has been a key driver of success.^{3–6}

That warnings can be impactful at decreasing sales has been underlined over decades by the tobacco industry's fierce lobbying against more effective warnings and by the commencement of legal challenges.^{3 7 8} Warnings have passed the 'scream test'. Tobacco industry opposition has sought to block, delay, weaken and overturn warning requirements.

Well-designed warnings decrease tobacco use and increase awareness of the health effects,² and are an effective government response to the under-awareness and underappreciation of the vast range of health consequences and their magnitude.^{2 9 10} This is especially the case given that most tobacco consumers begin as adolescents younger than the legal age, when they have even less awareness. Packaging has promotional value,^{11–15} and larger graphic warnings reduce the package's promotional impact and denormalise the product.

The evidence in support of the effectiveness of well-designed warnings, including the incremental effectiveness of larger warnings, and picture-based warnings instead of text-only warnings, was supported with evidence in Canada^{16–20} and has long been overwhelming and has increased over time.^{8 10 21–36} In a sense, research has proved the obvious. Health concerns are a key reason for quitting or considering quitting,^{37–39} and warnings provide health information. Indeed, if better warnings did not work, then why has the tobacco industry been so strongly opposed?

This paper aims to provide a historical overview of package warning developments, particularly over the last 30 years; to outline the role of the FCTC; to identify tobacco industry strategies and arguments that have been overcome; to identify other labelling issues; and to outline why tobacco package health warnings have seen such global success.

EARLY DEVELOPMENTS

Package health warnings first appeared in the 1960s and 1970s on a legislated or voluntary basis,

beginning with the USA in 1966.³ Warnings were initially located on the lateral side of cigarette packages, with a single warning using weak general language, with no mention of cancer, heart attacks or other specific health effects. In 1973, Australia required a warning on the front of the package, but with small text that could be in package colours.⁷ In 1977, Sweden required 16 rotated messages, with information on specific health effects, to appear in about 20% of the front or back using black on white or other dark on light colour^{40 41}; this lasted until 1993 when Sweden implemented European Union (EU) 4% text warnings.⁴² In 1993, Thailand required 10 rotated text warnings covering 25% of the package front and back.^{43 44} In 1994, Canada required eight rotated black and white text warnings in about the top 35% of the package front/back.^{45 46}

By 1996, there were at least 127 countries/jurisdictions with legislated or voluntary warnings.^{47 48} Although a large proportion of these countries still had a single weak warning, more and more were strengthening requirements.^{47–49}

THE IMPACT OF THE FCTC

When negotiations for the FCTC began in October 2000, only Canada had required warnings with graphic pictures, and had required a size of at least 50% of the package front/back.⁵⁰ When the FCTC was approved in May 2003, Brazil was the only other country to require picture warnings or to have at least a 50% size on average (Brazil had 0% front, 100% back).⁵¹

The FCTC, with 182 Parties as of September 2021, includes in Article 11 mandatory minimum requirements for Parties: warnings must be at least 30%—and should be 50% or more—of the principal display areas, which for cigarettes is the package front and back; pictures may be used; there must be rotated messages, rather than a single unchanging message; messages can include non-health messages; warnings must be in the language(s) of the country; the requirements apply to all categories of tobacco products. The FCTC itself recognises the fundamental importance of health warnings, with the FCTC's very first guiding principle stating in part, 'Every person should be informed of the health consequences, addictive nature and mortal threat posed by tobacco consumption and exposure to tobacco smoke'.²

FCTC Guidelines for implementation of Article 11 on packaging and labelling (FCTC Guidelines), adopted in 2008, recognise 'that the effectiveness of health warnings and messages increases with

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Figure 1 Number of countries/jurisdictions requiring warnings of 50% or more (on average) of the front and back of cigarette packages.⁵⁰

their size' and that Parties should 'aim to cover as much of the principal display areas as possible'.² The FCTC Guidelines also recognise that warnings 'that contain both pictures and text are far more effective than those that are text-only' and 'have the added benefit of potentially reaching people with low levels of literacy and those who cannot read the language(s)' of text-only warnings.²

The FCTC Guidelines, which represent an international consensus, recognise that 'well-designed health warnings and messages on tobacco product packages have been shown to be a cost-effective means to increase public awareness of the health effects of tobacco use and to be effective in reducing tobacco consumption'. This authoritatively counters industry misinformation that better warnings have no incremental impact.

In developing package warning provisions in the FCTC and later the FCTC Guidelines, governments had decades of experience in drafting warning requirements, observing industry strategies to undermine warnings and responding to these strategies. Non-government organisations, also with decades of experience, advocated for effective FCTC warning provisions.^{52–54}

The FCTC has helped to further revolutionise warning requirements internationally, with countries continuing a decades-long

Figure 2 Number of countries/jurisdictions requiring picture warnings on cigarette packages.⁵⁰

approach of improving on each other. The FCTC has added fuel to a spiral of upward government competition.

By at least 2008, in many countries Philip Morris International (PMI) was, in the absence of legislated warnings, voluntarily placing 30% text warnings in national languages on the package front/back, including in Africa, thus discouraging countries from legislating beyond FCTC minimum standards⁵⁵ (figure 3).

SIZE AND LOCATION OF WARNINGS

The size of warnings now being achieved in many countries was inconceivable 30 years ago. By October 2021, there were at least 122 countries/jurisdictions requiring warnings of 50% or more (on average) of the package front/back (figure 1); 27 had required at least 70%, and 10 had required at least 85%.^{50 56} The world leaders in warning size are:

- ▶ 92.5% Timor-Leste (85%, 100%).⁵⁷
- ▶ 92.5% Turkey (85%, 100%).
- ▶ 90% Maldives (90%, 90%).
- ▶ 90% Nepal (90%, 90%).
- ▶ 90% Vanuatu (90%, 90%).
- ▶ 90% Benin (90%, 90%), 2022.
- ▶ 87.5% New Zealand (75%, 100%).

Box 1 outlines how the world's largest health warnings have increased over time. Despite the progress, there remain at least 49 countries not meeting the FCTC 30% minimum, with most of these having no warning requirement at all to appear on the front/back.^{50 56}

Countries are increasingly requiring that warnings be placed at the top of front and back surfaces, and requiring that pictures be located on both the front and back. Further, more countries are requiring health warnings to appear on more sides in addition to the front/back. For example, the EU requires 'Smoking kills' or 'Smoking kills—quit now' to appear on 50% of a lateral side. Several countries require a series of rotated black on yellow text warnings on a lateral side, while Thailand requires these on both lateral sides (figure 5).⁵⁸ Timor-Leste (figure 3) and Nepal require warnings/messages to appear on five of six sides.

A more recent trend has been for countries to require a minimum surface area for warnings, in addition to a minimum percentage size (eg, EU, Australia, New Zealand). For 20 cigarettes, the largest minimum warning surface area for the front and back is 46.5 cm² in the Canadian province of Quebec (figure 4), followed by Canada at 43.6 cm².⁵⁰ (The surface area for the front and back of flip-top packages of 20 standard-length (~83–84 mm) cigarettes is typically about 49 cm², though this can vary. Canada requires cigarettes, effective February 2022, to be sold in the slide and shell package format,⁵⁹ which increases surface area compared with flip top (figure 4)). A minimum package width can have the effect in part to prevent the narrow superslims 'purse' pack formats (figure 4). Comoros (30.0 cm²) and India (14.0 cm²) apply the minimum warning surface area to all tobacco products, including smokeless tobacco and bidis.

USE OF PICTURES

A picture says a thousand words. That simple adage helps explain why, as of October 2021, there are at least 134 countries/jurisdictions that have finalised requirements for picture warnings (figure 2).^{50 56} Of the 20 most populous countries in the world, only four have not yet implemented picture warnings: China (though Hong Kong and Macau have pictures); USA (implementation pending); Japan; and Democratic Republic of the Congo.

Figure 3 Examples of tobacco package health warnings and labelling. (A) Pursuant to a 1989 Directive, the EU required text warnings of 4% in unilingual countries. (B) Sweden required text warnings of this type, 1977-1993. (C) Iceland required a rotated series of pictogram warnings, which appeared on the package back, with each pictogram in a different single colour. (D) PMI voluntarily placed this 30% text warning, "Smoking kills", in Angola.

Figure 4 Additional examples of tobacco package health warnings and labelling. (A) Two Switzerland packages with 20 cigarettes with same warning shown, with one Vogue Superslims 100mm. (B) All Canadian cigarette packages are required to be slide and shell format as of 7 Feb 2022, which increases warning surface area. The two Canadian packages shown each have 25 cigarettes. (C) Though Canada requires a 75% warning size, Quebec (Canadian province) requires a minimum warning surface area of 46.5 cm², which increases the size to 93% on this 75 mm high package. (D) This row includes messages on plastic in filters and the environment (Germany/EU, 6%), fire risk (Australia, 10%), saving money by quitting (Jamaica), and secondhand smoke and pets (Panama). (E) Example of Turkey's required warning on waterpipe bottles in restaurants/cafes, but this is not enforced. (F) Singapore tax marking on cigarettes, "SDPC" (Singapore Duty Paid Cigarettes).

Warnings with graphic pictures were first implemented in Canada in 2001.^{60–62} At the time, the industry argued in part that it was technically impossible to print colour pictures on packages in Canada.^{63–64} The industry repeated this argument in Brazil and other countries proposing picture warnings earlier on^{8–65} with the argument only abandoned when lacking any credibility as more and more countries required pictures. The industry itself has used pictures on packages for promotional purposes.^{66–68}

Earlier, Iceland had required one-colour pictogram warnings (figure 3), which appeared on the package back, from 1985 to 1996, after which EU 4% text warnings were implemented.^{3–41}

WARNING CONTENT AND ROTATION

Global experience has seen a wide variety of content for warnings, including messages for dozens of different health effects. Many messages are needed because of the number of health effects and because different messages are applicable to, and resonate with, different people. A country's overall warning system should effectively convey the health risks and their magnitude.

Pictures can present vivid, unavoidable images of health harms. Evidence supports very graphic, hard-hitting picture warnings as effective at discouraging smoking, increasing impact, including for risk perceptions and quit intentions.^{10–69–73}

Box 1 Evolution of world's largest cigarette package health warnings.

This outlines the historical evolution of the countries requiring the largest cigarette health warnings in the world, identifying chronologically when a country had become the new world leader with the largest size.⁵⁰ The listing is based on the average size for the package front and back. The percentages in parentheses indicate the required size on the front and on the back.

20% Canada, 1989 (20% front, 20% back).⁴⁶

25% Thailand, 1993 (25%, 25%).^{43 44}

29% Australia, 1995 (25%, 33%).

30% Poland, 1998.¹⁹⁰

35% Canada, 1994 (including border).^{*45 46}

50% Canada, 2001 (50%, 50%).^{60–62}

56% Belgium, 2003 (including border).^{*}

60% Australia, 2006 (30%, 90%).¹⁹¹

65% Mauritius, June 2009 (60%, 70%).¹⁹²

80% Uruguay, November 2009 (80%, 80%).

82.5% Australia, 2012 (75%, 90%).

85% Thailand, 2014 (85%, 85%).⁴⁴

90% Nepal, 2015 (90%, 90%).¹¹⁸

92.5% Timor-Leste, 2018 (85%, 100%).⁵⁷

*Warning size including the border surrounding the warning varied somewhat based on package format.

By the late 1990s, PMI said it would defer to health authorities regarding warning content, but for picture warnings in 2000 PMI took the position that the Canadian warnings were 'using full color "shock images" designed to disparage the product and to make the products' packaging repulsive. The label is not about information but denigration'.⁷⁴ PMI would later object to warnings in Brazil on the grounds that they were too shocking,^{75 76} a further sign of effectiveness.

Complementing warnings having strong graphic images with messages that support cessation, such as pack inserts providing cessation tips, could aid quitting-related responses.^{77–81} Many countries have warnings that include toll-free quitline numbers, which can lead to a substantial increase in calls.^{82–89} Many warnings also include a website address. Costa Rica requires a large QR code on the package back (figure 3).

In determining warning content, messages used in other countries can be assessed for potential use. Messages can target different subpopulations (eg, youth, male/female). Further, warnings can support other tobacco control measures. For example, secondhand smoke warnings can support smoking bans in public places. Messages on the cost of buying cigarettes complement higher tobacco taxes given that such messages can remind/emphasise to consumers how much is actually being paid (eg, per year).

Some countries have required non-health messages, such as money saved by quitting (Ecuador, Jamaica, Saint Lucia, Trinidad and Tobago, Argentina, EU,⁹⁰ Djibouti⁹¹); compliance with ignition propensity regulations ('Australian fire risk standard compliant. Use care in disposal', Australia⁹²); secondhand smoke and pets (Panama); cigarette butts and ocean pollution (Argentina); and plastic in filters and the environment (EU)⁹³ (figures 4 and 5).

The number of rotated messages appearing concurrently has not exceeded 16, which Canada has done since 2001, though some countries have additional messages on a lateral side or

side other than front/back, and Canada has interior messages. The EU has three sets of 14 warnings changed annually, and in the 1990s had two on the front and a choice of up to 15 on the back.⁹⁰ Australia and New Zealand have had two sets of seven messages changed annually, with some other countries also having multiple sets. Pakistan, India, Myanmar and Iran are examples where only one picture warning has appeared at a time, though changing periodically.

For most countries, warnings are not refreshed frequently enough, which leads to wear out and reduced impact over time.^{38 94 95} Some countries, such as Australia and Canada, have gone a decade in between changing warning requirements. However, some countries have had nine or more rounds of picture warnings, including Ecuador, Colombia, Mexico, Panama and Uruguay.⁵⁰ Countries should have a continuous warning system such that a next set of warnings is always ready or in preparation. Having a large number of warning messages appearing concurrently, and continuously and frequently changing the required set of messages (at least annually), are necessary to inform consumers of the extensive array of health effects and to reduce wear out. Additional approaches to reduce wear out and attract consumer attention can include varying design elements and using prominent colours for the text portion of warnings.

INDUSTRY UNDERMINING OF WARNINGS

Over decades, the tobacco industry has undermined warnings in many ways, including by having a voluntary warning to deter stronger regulation; having voluntary warnings in a foreign language (English); using weak message content; minimising warning size, prominence and visibility including through the choice of colours and package location; having deficient print quality for colour images; having warnings stretch over bevelled edges; and marketing 'slims' packages and various novel package formats, which impair warnings.^{3 8 96–99}

INDUSTRY ARGUMENTS

In opposing strengthened warnings, the industry has used many arguments, including: existing warnings (sometimes voluntary warnings) are adequate; it is not proven that better warnings would be more effective; people already know the health effects; smokers would be 'demonized' and treated like outcasts; it would cost the industry too much; governments wanting these messages should pay for mass media advertising; it would infringe on the ability to adequately brand the product; the requirements would be legally invalid; there would be increased contraband.^{8 65 100–102} The industry has argued that large warnings infringe intellectual property protection in the World Trade Organization and other international trade agreements, but with the upholding of Australia's plain packaging¹⁰³ this cannot be a valid argument. Governments have been able to overcome all these arguments. As to contraband, prominent warnings unique to a country in national language(s) actually make it easier to identify illegal product.

INDUSTRY LEGAL CHALLENGES

The tobacco industry has threatened and commenced legal challenges as a means to deter and overturn more effective package warnings. Arguments have varied but have included: freedom of expression; the regulation not being authorised by the enabling statute; countries subject to EU requirements cannot have more stringent provisions; expropriation/infringement of trademarks/brands/intellectual property rights; and infringement of a trade agreement(s). Overwhelmingly, legal challenges have been

Figure 5 Examples of messages appearing on inserts, onsets and lateral sides of cigarette packages. (A) The Canadian inserts in flip-top packages in the 2001 and 2012 rounds were required to be visible when the package was opened. The inserts were bilingual, English on one side, French on the other. Interior messages were also required for packages in slide and shell format. With the new 2022 Canadian mandatory requirement for the slide and shell format, interior messages will thus only appear on the slide. (B) A US onset appearing 2018–2020. The onset was under the cellophane and glued to the back of the package. The package could be opened without removing the onset (by using the tear tape to remove the top part of the cellophane). The onset would open to have eight panels, four on each side, with English on one side (four panels) and the cover, and Spanish text (three panels) on the other.

dismissed, including in the UK (6% text, larger than EU 4%),¹⁰⁴ Germany (text warnings),¹⁰⁵ EU (text 30% front, 40% back, 2002; 65% pictures, 2016),^{106–108} Philippines (25% text),^{109 110} Canada (50% pictures),^{111–113} Uruguay (80% pictures),^{114 115} Indonesia (40% pictures),^{116 117} Nepal (75% pictures),¹¹⁸ Thailand (85% pictures),¹¹⁹ Sri Lanka (80% pictures),¹²⁰ Brazil (pictures, 100% one side),^{65 76} Kenya (pictures, 30% front, 50% back),^{121–123} India (85% pictures)^{108 124 125} and Uganda (65% pictures),¹²⁶ among others.

However, US courts have held that while 50% picture warnings could be justified, the specific pictures adopted in 2011 and the requirement to depict the quitline number 1-800-QUIT-NOW were invalidated (2012).^{127–129} The USA adopted new 50% pictures in 2020, followed by new industry litigation still in progress. In Paraguay,¹³⁰ Philippines¹³¹ and Turkey,¹³² warnings were invalidated for administrative reasons, but these countries each successfully responded with replacement picture warning requirements.

TOXIC EMISSION MESSAGES AND MISLEADING DESCRIPTORS

While in the past many countries required tar, nicotine and sometimes carbon monoxide yield numbers on packages, usually appearing on a lateral side, FCTC Guidelines recommend against this because of the misleading nature of these yields.^{2 133} Instead, many countries now require qualitative toxic emission messages with no quantitative emission indications (figure 5). At the same time, a 2021 analysis of laws of 129 countries/jurisdictions found 38 still requiring tar/nicotine yield numbers on packages.¹³⁴

Separate from a legislated requirement for emission yield numbers on packages, at least 58 countries have, as the FCTC Guidelines recommend,² banned companies from being able on their own to place yield numbers on packages.⁵⁶

Beginning with Brazil in 2001,^{135 136} at least 137 countries/jurisdictions specifically prohibit 'light' and/or 'mild' descriptors for at least cigarettes,⁵⁶ and often other specific terms, because of their misleading nature, as outlined in FCTC Guidelines.^{2 137} Among examples of jurisdictions banning specific descriptors beyond 'light' and 'mild', the EU has banned 'low-tar', 'ultra-light', 'natural', 'organic', 'without additives', 'without flavours' and 'slim'.¹³⁸ Canada bans reference to a colour or a filter characteristic.^{59 139}

INSERTS

One country, Canada, has required package inserts, with eight rotated messages, initially required in 2001–2012 with 16 rotated messages (figure 5). In Israel, 2019 legislation includes regulatory authority to require inserts,¹⁴⁰ and a working group has been established to develop insert content. In Mexico for a period, by a 2004 voluntary agreement, onsets appeared outside 25% of packages under the cellophane (figure 5).¹⁴¹ In the USA intermittently over a 24-month period during 2018–2020, five onsets with corrective health messaging appeared pursuant to a court order (figure 5).^{142 143} Inserts can provide additional information on health effects as well as cessation information.

PLAIN PACKAGING

Plain packaging, which in itself makes tobacco products less appealing and discourages tobacco use, also complements and enhances the effectiveness of package warnings. In this issue, Moodie *et al* provide an overview of the critical importance of plain packaging.¹⁴⁴ At least 21 jurisdictions have finalised plain

packaging requirements as of October 2021,⁵⁰ though some do not apply plain packaging to all tobacco products.

SINGLE PRESENTATION REQUIREMENT

One country, Uruguay in 2008, has adopted a single presentation requirement, such that there can only be one brand variation sold per brand family. Thus, for Marlboro there can be only one of Marlboro 'Red', 'Gold', 'Silver' or Menthol, etc, thereby curtailing brand variant names and package colours creating deceptive impressions.^{145–149} Industry legal challenges to the Uruguay requirement were dismissed.^{114 150}

WARNINGS ON CIGARETTES THEMSELVES

Research indicates that warnings directly on cigarette sticks have tremendous potential and would be an effective measure to discourage smoking and increase quitting.^{151–162} A health warning would be there for every puff of every cigarette. Though included in FCTC Guidelines,² no country has yet required a warning on the cigarette itself. Canada consulted on the measure in 2018,^{163–165} and a private member's bill was introduced in the UK Parliament in 2021.¹⁶⁶ Singapore has required a tax-paid marking on cigarettes since 2009 (figure 4).^{167 168}

SMOKELESS TOBACCO

Smokeless tobacco has substantial consumption rates in some countries. By 2020, at least 47 countries required picture warnings for smokeless tobacco, 42 of which required a size of at least 50%.^{56 169} Smaller package sizes can represent an issue in developing warnings.

WATERPIPE TOBACCO

Waterpipe smoking is popular in certain countries, and with specific population groups in some other countries.¹⁷⁰ Some studies have considered warning options for the device itself in addition to packaging.^{171–175} Turkey has required a rotated series of health warnings to be displayed on waterpipe devices in public settings such as cafes/restaurants^{176–178} (figure 4), but this has not been enforced. Nigerian regulations include health warnings on waterpipe devices, but compliance levels have not been confirmed.¹⁷⁹

ELECTRONIC CIGARETTES AND NOVEL PRODUCTS

Going forward an issue for countries is to determine appropriate health messages for newer product categories such as electronic cigarettes, heated tobacco products and nicotine pouches. Determining appropriate messages for longer standing product categories may also apply, such as smokeless tobacco and waterpipe tobacco, which in some markets may be newer. The FCTC Guidelines recommend that governments consider health messages appropriate for the particular tobacco product category.²

WHY WARNINGS HAVE BEEN A SUCCESSFUL MEASURE

There are a series of reasons why the global movement to larger, picture-based, more impactful warnings has been so successful. Of note, the cost is paid by industry, not government, which is especially attractive for low and middle-income countries. The measure is effective and has broad national reach, reaching every tobacco consumer many times per day, as well as family, friends and coworkers of the consumer. The measure is simple to understand, permanent and can be modified/enhanced over time. Warnings can be politically attractive and announced by

health ministers, which itself generates media coverage and public awareness of health effects.

From a regulatory perspective, countries already have experience with package warnings, better warnings are a logical next step and there is an absence of credible arguments against. Countries also have access to resources and international cooperation to make things even easier, including websites providing information and describing international practices,^{180–184} technical assistance in drafting laws¹⁸⁵ and other countries willing to license pictures for free. For tobacco companies, they normally have tremendous difficulty in mobilising others to oppose better warnings.

Finally, there is substantial international pressure to enact warnings. Governments do not want to be left behind regionally/internationally. An industry trade journal referred in 2010 to ‘countries vying to outdo each other... “Mine is bigger than yours” is the motto’.¹⁸⁶ Countries are publicly scrutinised, including through global summary reports,^{50 56 187 188} and the FCTC reporting process.¹⁸⁹ The WHO has actively supported better warnings, including through WHO regional and country offices, while non-government organisations have been effective in advocacy for better warnings, in country after country.

LOOKING TO THE FUTURE

Despite the tremendous progress achieved, no country has yet come close to implementing a full, comprehensive and necessary tobacco health warning system. Countries need to, and will, improve through larger sizes; standardising package format and increasing warning surface area; increased use of the package exterior (such as requiring messages on five of six cigarette package sides); improved rotation both in terms of increasing the number of messages appearing concurrently and the frequency with which sets of warnings change; inserts/interior messages with both health warning and cessation content; innovative and enhanced message content, including newly covered health effects (eg, diabetes, cleft palate) and non-health messages, as well as new attention-getting means of conveying messages; messages directly on cigarettes/products themselves; and complementary implementation of plain packaging.

CONCLUSION

The history of tobacco package health warnings, already an enormous accomplishment, is just beginning. Package warning and labelling requirements reach all tobacco consumers, 24 hours/day, 365 days/year, and are a well-established, evidence-based, low cost and highly effective means at reducing tobacco use. Government recognition of this can only increase. Though clearly not all tobacco consumers will quit because of warnings, package health warnings are, and will remain, a crucial and permanent tool for successful tobacco control. The best is yet to come.

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ORCID iD

Rob Cunningham <http://orcid.org/0000-0003-2219-2384>

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