BEFORE THE BOARD OF COMMISSIONERS OF LANE COUNTY, OREGON
SITTING AS THE LANE COUNTY BOARD OF HEALTH

ORDER NO: 15-08-25-01	IN THE MATTER OF APPROVING SUBMISSION OF COMMENTS TO THE FOOD AND DRUG ADMINISTRATION ON THE EXTENSION OF THE AGENCY'S AUTHORITY TO REGULATE ADDITIONAL TOBACCO PRODUCTS AND RELATED ACTIONS

WHEREAS, the Board of County Commissioners of Lane County acting in its capacity as the Lane County Board of Health has a stated interest in promoting the public's health and in protecting its young; and

WHEREAS, the Board supports the Federal and Drug Administration's (FDA's) goal of making the "next generation tobacco-free"; and

WHEREAS, the Board has enacted Ordinance 14-19, addressing Tobacco Regulation, including e-cigarettes, in Lane County;

NOW, THEREFORE, the Board of County Commissioners of Lane County **ORDERS** as follows:

1. that the Department of Health & Human Services be authorized to submit the attached letter, signed by the Board Chair and the County Health Officer, on the proposed FDA Rulemaking related to the "deeming" of "tobacco" products, Docket No. FDA-2015-N-1514.

ADOPTED this 25th day of August, 2015

Jay Bozievich, Chair
Lane County Board of Commissioners

APPROVED AS TO FORM
Date 8/14/15
LANE COUNTY OFFICE OF LEGAL COUNSEL

LANE COUNTY
PUBLIC SERVICE BUILDING, 125 EAST 8TH AVENUE, EUGENE, OR 97401/(541) 682-4203/FAX (541) 682-4616

August 25, 2015

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
Submitted via the Federal eRulemaking Portal

Re: Docket No. FDA-2015-N-1514
Nicotine Exposure Warnings and Child-Resistant Packaging for Liquid Nicotine, Nicotine-Containing ELiquid(s), and Other Tobacco Products; Request for Comments

Dear Sir or Madam:

The Undersigned, acting as the Chair of and commenting on behalf of, the Lane County Board of Commissioners, sitting as the Lane County Board of Health, submits this Comment in Response to the Food and Drug Administration's (FDA's) Advanced Notice of Proposed Rule, referenced above, dated July 1, 2015. We support the FDA's implementation of nicotine exposure warning labels and child-resistant packaging and provide these relevant Comments, based upon Lane County's experience with respect to the subject of the proposed rulemaking.

The first priority in our Strategic Plan for Lane County is to ensure a safe and healthy county, and a priority of our Community Health Improvement Plan (CHIP) is to prevent and reduce tobacco use, which includes regulation of electronic nicotine delivery systems and nicotine liquids. Lane County, with a population (356,125) that accounts for ten percent (10%) of the state's population and a large diverse geography that extends from the Cascade Mountains to the Pacific Ocean, faces many challenges and localized disparities in its efforts to protect the public's health. For instance, the Cities of Florence, Oakridge, and Cottage Grove, rural areas of the county, have much higher tobacco use rates, including during pregnancy (30% use during pregnancy in Oakridge versus 13% in the Eugene urban area), and carry a higher burden of tobacco-related diseases and deaths.

We do not seek to report the established facts regarding the need to prevent tobacco/nicotine use among youth and to support cessation among established users, already addicted to this dangerous substance and the many harmful chemicals that accompany it, based on the selected delivery system. We do, however, take this opportunity to provide the following corroborating testimony supporting the need to provide for child-resistant packaging and warning labels on nicotine liquids and novel tobacco products.

A. Nicotine Exposure Warnings

1. Should FDA consider requiring nicotine exposure warning(s) text on liquid nicotine? If so, why?

Lane County supports the FDA requiring nicotine exposure warning text on liquid nicotine. The State of Oregon does not have such a requirement. The majority of Lane County tobacco and e-cigarette retailers market in ways that appeal to youth. Youth are primarily attracted to the variety of e-cigarettes flavors available. The marketing approach is making these nicotine products easily obtainable, more attractive and markedly pleasing to the eye and misleading them creating misconceptions about them the health effects of nicotine. The youth are using them at an alarmingly increasing rate.

In Lane County's 2014 assessment of retailers selling these products, 61% of the retailers were found to be placing products and advertising in ways that target youth (i.e. within 12 inches of products sold to youth like toys and candy or at a child's eye level within 3 feet of the floor). Use of e-cigarettes among 11th grade students in Oregon nearly tripled from 2011 to 2013 (from 1.8% to 5.2%, respectively). In Lane County, the youth smoking rate has stabilized, while youth use of e-cigarettes and other tobacco products, that tend to be flavored, is increasing.

Numerous reports have been received from community members that their children have at least tried these devices, arguing that these devices are harmless because that is what they have been told by industry marketing. One local high school student told staff that these products are easy to obtain, and he and his friends get them from other friends and family members who are age 18 and over.

In Oregon, the leading source of tobacco and e-cigarettes for youth is friends; first, those age 18 and older, and then, those younger than 18 (34.2% and 27.6% for 8th graders and 51.8% and 19.9% for 11th graders, respectively). A recent *Pediatrics* study reports that over 40% of youth e-cigarette users had never smoked a cigarette, and nearly half of youth e-cigarette users did not believe e-cigarettes had any health risks. Youth who reported home use of e-cigarettes or friends' use of and positive attitudes towards e-cigarettes were much more likely to use e-cigarettes. Results suggest that e-cigarette use is becoming more normalized and may be leading to the renormalization of smoking.[1]

The American Chemical Society Journal *Chemical Research in Toxicology*, reports that much of the nicotine in e-cigarettes is in the most addictive form of the compound.[2] Although many of these products are marketed as cessation tools, the use of highly addictive compounds (i.e. nicotine) helps perpetuate the addiction and makes it harder to quit smoking.[3]

The limited testing completed to-date, has demonstrated a wide range of inconsistent nicotine concentrations, even within product lines, making consumer use of these

products uninformed and, potentially, dangerous. Most e-cigarettes are made overseas where manufacturing and safety standards may differ, making it more difficult to know what is in e-cigarettes without regulation.[4]

Nicotine is addictive and harmful. Companion and contaminant compounds in these products, though not addictive, have been known to cause cancer and birth defects.[4]

2. **Should FDA consider requiring nicotine exposure warning(s) text on tobacco products other than liquid nicotine, including, but not limited to, novel tobacco products? If so, which products and why?**

   Lane County supports exposure warnings on all nicotine-containing products regulated by the FDA, based on the dangers related to topical absorption (gels and related products) and ingestion (liquids/dissolvables). All nicotine exposes users to the risk of addiction and potential harm to their health. Exposure to nicotine by swallowing or contact with the skin can result in nausea and vomiting, as well as respiratory arrest, seizures, or even death.[5]

   Given the significant increase in youth use of tobacco products that tend to be flavored and their misunderstanding of the risks associated with the products due to the industry's aggressive marketing tactics, as discussed above in Item A.1, the need to require nicotine exposure warning text on all nicotine-containing and tobacco products is dire.

3. **On what basis (e.g., physical characteristics or appearance of the product or packaging, product risks, form of marketing, route of exposure, type of packaging) should FDA determine which products should be required to carry the warning(s)? What data or information would be helpful to demonstrate the need for a warning or warnings?**

   As stated above in Item A.2, Lane County supports the application of warnings to all products based on nicotine or tobacco content. The presence of nicotine or tobacco creates the need for the warning(s).

4. **If FDA were to require nicotine exposure warning(s) text for liquid nicotine, what issues should the warning(s) address and what wording should be used? Please consider: (a) Whether the warning(s) should be broad, or directed at specific dangers; (b) whether the warning(s) should specifically address oral, ocular, and dermal exposure dangers; (c) whether the warning(s) should focus exclusively on the risks to children and youth, or include the risks to vulnerable populations, such as pregnant women, adults with medical conditions, and pets; (d) whether the warning(s) should contain instructions to avoid the dangers altogether, such as "keep out of the reach of children"; (e) whether there are other dangers of liquid nicotine exposure that should be covered by the warning(s); and (f) whether information about what to do in the case of an accidental exposure to liquid nicotine should be included (e.g., when to seek**

medical attention, when to contact a Poison Control Center). Please submit data or evidence to support your position.

Lane County supports the FDA in using nicotine exposure warning text for liquid nicotine to address oral, ocular, or dermal exposure; including broad instructions to "keep out of the reach of children"; placing warnings for adults about potential harms from accidental or intentional misuse; and including the national poison control number. Where feasible, standard symbols and warnings, such as those endorsed by the U.S. Pharmacopeial Convention, would be helpful for limiting confusion. Warnings should also be developed to address specific risks to vulnerable populations, including children, youth, pregnant women, adults with medical conditions, and pets; however, warnings should not exclude the broader adult population about the dangers of nicotine exposure. Nicotine can cross the placenta and exposure during the developmental periods can lead to impairment of brain development and therefore changes to the brain architecture, chemistry and behavior. It is estimated to cause 5.3-7.7% or preterm births and 23.2-33.6% of SIDS death in the USA.

5. **With preceding question 4 in mind, should there be multiple textual warnings that randomly display to convey different dangers, or should there be a single, consistent textual warning that covers all of the different dangers? Please submit data or evidence to support your position.**

   Lane County supports the use of warning labels that are rotated regularly to avoid overexposure and a reduction in effectiveness.[6] However, acute dangers should be consistently included, along with instructions to "keep out of the reach of children."

6. **If FDA were to require nicotine exposure warning(s) text for tobacco products other than liquid nicotine, including, but not limited to, novel tobacco products, what issues should the warning(s) address and what wording should be used? Please consider: (a) Whether the warning(s) should be broad, or directed at specific dangers; (b) whether the warning(s) should specifically address oral, ocular, and dermal exposure dangers; (c) whether the warning(s) should focus exclusively on the risks to children and youth, or include the risks to vulnerable populations, such as pregnant women, adults with medical conditions, and pets; (d) whether the warning(s) should contain instructions to avoid the dangers altogether, such as "keep out of the reach of children"; (e) whether there are other dangers of nicotine exposure that should be covered by the warning(s); and (f) whether information about what to do in the case of an accidental exposure to liquid nicotine should be included (e.g., when to seek medical attention, when to contact a Poison Control Center). Please submit data or evidence to support your position.**

   A review of the evidence on the impact of tobacco warning labels found that the warning label characteristics described below are noticed more, are an important

source of health information, increases knowledge about tobacco use harms and perceptions of risk, and promote cessation. There is evidence that comprehensive warning labels are effective among youth and prevent smoking initiation.[7] Therefore, Lane County supports the following labeling recommendations for tobacco products:

1. Require warning labels large enough to be easily noticed and read.[8]
2. Require warning labels to appear on the front, compared to the side, of packages.[9]
3. Require warning labels be clear, direct and accurate about the dangers of tobacco use, including messages about specific health effects.[6]
4. Require warning messages that are worded simply and speak directly to the reader.[6]
5. Require warnings with color pictures.[10]
6. Require warning labels that include graphic images that elicit an emotional response.[11]
7. Require warning labels be rotated regularly to avoid overexposure.[6]
8. Require warning labels include information for those who want to quit using tobacco (e.g. the Tobacco Quit Line phone number 1-800-QUIT-NOW).[6]
9. Prohibit all health claims or descriptors.

7. **With preceding question 6 in mind, please respond to the following questions: Should there be multiple textual warnings that randomly display to convey different dangers, or should there be a single, consistent textual warning that covers all of the different dangers? Should different types of tobacco products carry different warnings? If so, which type(s) of tobacco products should carry what warning(s) and what is the reasoning for different warnings for different types of tobacco products? Please submit data or evidence to support your position.**

Lane County supports the use of warning labels that are rotated regularly to avoid overexposure and a reduction in effectiveness, as stated in Item A.5 above.[6] However, acute dangers should be consistently included, along with instructions to "keep out of the reach of children."

Different types of tobacco products should carry different warnings, depending on the risks associated with each one. For instance, while liquid nicotine products have oral, ocular, and dermal absorption risks, dissolvable tobacco products do not have the same risks.

8. **If FDA were to require nicotine exposure warning(s) text for liquid nicotine, should FDA consider requiring color(s) or graphic elements, such as symbols, as part of the warning(s)? If so, what color or graphic elements should FDA consider?**

Lane County supports nicotine exposure warning labels with color pictures, as mentioned above in Item A.6. Warnings with pictures are more effective than text-only warnings. Pictures increase the accessibility of the message by people who have

low literacy levels and can help people visualize the risk. Color pictures are more effective than black and white pictures.[10]

9. **If FDA were to require nicotine exposure warning(s) text for tobacco products other than liquid nicotine, including, but not limited to, novel tobacco products, should FDA consider requiring color(s) or graphic elements as part of the warning(s)? If so, what color or graphic elements should FDA consider?**

   Lane County supports the combination of nicotine exposure warning text labels with color pictures, as mentioned above in Items A.6 and A.8. Warnings with pictures are more effective than text-only warnings. Pictures increase the accessibility of the message by people who have low literacy levels and can help people visualize the risk. Color pictures are more effective than black and white pictures.[10]

10. **If FDA were to require a nicotine exposure warning(s) (text and any applicable color or graphic element) for liquid nicotine, should FDA adopt a different nicotine exposure warning(s) requirement based on the packaging/containers (e.g., a brief/abbreviated warning(s) for liquid nicotine in small packaging/containers, omit the warning(s) if the tobacco product is in a child-resistant package)? If so, how should the warning(s) differ? Please submit data or evidence to support your position.**

    As mentioned above in A7, different types of tobacco products carry their own risks and should carry different warnings. A study published in the journal *Pediatrics* showed that occurrence of toxic symptoms occurred after exposure to patches that were bitten, chewed, or swallowed in children younger than 16 years old (averaging 3 years olds) was associated with an estimated nicotine dose greater than 0.10mg[12]. In terms of liquid nicotine, the pediatric lethal dose is 1.0 mg of nicotine per kilogram of body weight.

    Lane County does not support omitting the warning(s) on child-resistant packages.

11. **With respect to tobacco products other than liquid nicotine, including, but not limited to, novel tobacco products, if FDA were to require a nicotine exposure warning(s) (text and any applicable color or graphic element), should FDA adopt a different nicotine exposure warning(s) requirement based on the packaging/containers (e.g., a brief/abbreviated warning(s) for tobacco products in small packaging, omit the warning(s) if the tobacco product is in a child-resistant package)? If so, how should the warning(s) differ? Please submit data or evidence to support your position.**

    Please see above A10. Lane County does not support omitting the warning(s) on child-resistant packages.

12. **Are you aware of data or information that would support any required font**

sizes, formatting, and display considerations for nicotine exposure warnings (textual and/or graphic)? If so, please provide that evidence.

Lane County supports using evidence-based warning labels with the characteristics outlined in Item A.6. Fonts should be large enough to easily and clearly read and color pictures that elicit an emotional response.

13. **Should FDA require the inclusion of the American Association of Poison Control Centers' telephone number on the container labeling and/or packaging of liquid nicotine and tobacco products other than liquid nicotine? Why or why not?**

Lane County supports the FDA in requiring the inclusion of the American Association of Poison Control Centers' (AAPCC) telephone number on the container labeling and/or packaging of liquid nicotine and tobacco products other than liquid nicotine. This is the fastest way for an affected person to report exposure and to receive appropriate help. AAPCC has been tracking the increase in liquid nicotine exposures since 2010, and directing exposed individuals to report to the National Poison Data System will assist all states in monitoring and responding to the epidemiology of exposure.

14. **Are there any nicotine exposure warnings (textual and/or graphic) for liquid nicotine required by authorities at the local, State, or Federal (i.e., other agencies) level, or by foreign governments that you particularly would like to highlight? If so, which ones and why? Are there any data regarding the effectiveness or utility of these warnings? If so, please provide these data.**

It should be noted that the State of Oregon is drafting administrative rules per recently passed HB 2546 for inhalant delivery systems. Labeling (including warnings) is a required component.

15. **Are you aware of any existing evidence regarding whether warnings (text and any applicable color or graphic element) are effective for mitigating the risks of nicotine exposure? If so, please provide that evidence.**

Research in Canada supports messaging that occupies at least 75% of the package area. Several studies have reported that large font is necessary. Colors and graphics make the warning more accessible to a broader public. A broad "boxed" format has also been demonstrated to be more effective. [13]

B. Child-Resistant Packaging

1. **Should FDA require child-resistant packaging for liquid nicotine? If so, why?**

Lane County supports the requirement of child-resistant packaging for liquid nicotine.

FDA can require the use of child-resistant packaging for all e-liquid containers and provide enforcement for this requirement nationwide. By providing a minimum national standard, the e-liquid industry will have one consistent standard to meet or surpass, and states can explore options for additional regulation or enforcement, as needed.

Despite the introduction of federal legislation (S. 142) that would require the Consumer Product Safety Commission to create e-liquid specific child-resistant packaging rules, this may not be necessary as existing statue already defines how child-resistant packaging for any product must be created per the Poison Prevention Packaging Act of 1970, Public Law 91-601, and 16 CFR Part 1700. Many states are beginning to include such requirements in state law, but many are missing an enforcement mechanism. This is resulting in a national patchwork of regulation and inconsistent or nonexistent enforcement. The potential child-resistant packaging requirement may be inadequate if it only applies to e-liquid specifically advertised or labeled as containing nicotine. Given quality-control issues associated with e-liquid manufacturing (in which liquid advertised as containing no nicotine has been found to contain nicotine) documented by the FDA in 2010 and in 2015 by UC Riverside, all e-liquid containers should be sold in child-resistant packaging.

The number of calls to poison control centers for e-cigarette exposures by mouth in the USA increased from 1 call per month in September 2010 to 215 calls per month in February 2014. In 2014, poison control centers in the United States received 3,783 calls as a result of negative reaction to liquid nicotine. For children, this exposure can be fatal, as just one teaspoon represents a lethal dose. In Lane County, there were five reported cases (children under the age of 6) in 2014 and there has been two poisonings in 2015.

Children are drawn to e-liquid because of its many kid-friendly flavors. There are over 7,000 flavors available. According to the 2014 Lane County assessment of tobacco and e-cigarette retailers, 85% of the 311 retailers sell e-cigarette or e-liquid products. Of the retailers that sell e-cigarettes and e-liquid, 70% sell flavored e-liquid. An additional 11 retailers (that we are aware of) are vape shops that sell only e-cigarette or e-liquid products, and at least most of them sell flavored e-liquid.

Staff from the Lane County Women, Infants, and Children (WIC) Program had a client recently state that she uses e-cigarettes, and the client's toddler picked up her e-cigarette and pretended to vape it. The client has since been keeping them out of reach of her child. Staff from one of the Lane County home visiting programs had a client who stated that they use e-cigarettes and blow the "vapor" in their toddler's face because the toddler likes the sweet smell.

2. **Should FDA require child-resistant packaging for liquid nicotine if the liquid nicotine product is not intended to be opened by the consumer (e.g., liquid nicotine in permanently sealed, prefilled, and/or disposable cartridges)? Please provide the reason for your response.**

Lane County supports that all potentially harmful/lethal products brought into a home with young children be packaged to protect children from unintentional exposure. The issue is not how the nicotine is packaged, but who the intended (or unintended) user may be. It is also the fact that nicotine is present in the product, and in any form, nicotine is dangerous. This by itself should dictate the necessity for child-resistant packaging. Child-resistant packaging also serves as a warning to adults that the product inside is inappropriate and dangerous for children. This message should hold for nicotine, regardless of form, package, or seal.

3. **Should FDA consider requiring child-resistant packaging for tobacco products other than liquid nicotine, including, but not limited to, novel tobacco products? If so, which ones and why?**

Yes, Lane County supports child-resistant packaging for tobacco products other than liquid nicotine, including but not limited to, novel tobacco products. All forms of nicotine should be in child-resistant-packaging and include nicotine exposure warnings, due to the danger nicotine poses to children, pets, or adults in any form.

4. **If FDA were to require child-resistant packaging for liquid nicotine (including for those products that are not intended to be opened by the consumer), what type of exposure risks (e.g., oral, ocular, dermal) should FDA seek to mitigate with the requirement?**

In addition to topical skin irritations, nicotine is readily absorbed through skin and lungs and therefore topical exposure results in poisoning, similar to ingestion for children. Just as nicotine patches deliver intra-dermally, so does accidental spilling/touching of liquid nicotine. Exposure to the eyes, by touching or via spillage results in pain/burning, redness and general irritation. The substances are sticky, making multiple-site transference possible.

5. **If FDA were to require child-resistant packaging for tobacco products other than liquid nicotine, including, but not limited to, novel tobacco products, what risks (e.g., oral, ocular, dermal) should FDA seek to mitigate with the requirement?**

With a pediatric lethal dose of 1.0 mg of nicotine per kilogram of body weight, ingestion of these products remains the most important delivery method to be mitigated. Dissolvables and gels easily provide the opportunity for dermal contact and/or exposure to eyes, rendering children vulnerable in the same manners as mentioned in Item B.4, above.

6. **Are there other factors FDA should consider to further prevent or discourage people (especially infants and children) from inadvertently consuming or being exposed to liquid nicotine? If so, please explain. Examples of other factors may include: attractiveness of the product or packaging (e.g., appealing images,**

fragrance, flavors), resemblance of packaging to food and drink items (e.g., candy, fruit), color of the product (e.g., resemblance to beverages such as juice), resemblance of packaging to that of medications (e.g., eye drops).

Lane County supports the FDA in prohibiting packaging, flavors, and scents for e-cigarettes and nicotine liquids that may be attractive to children as a means of discouraging liquid nicotine exposure. Past experience in tobacco control shows that flavoring and cartoon and celebrity marketing imagery are clear industry marketing tactics intended to entice children and youth to try tobacco products.

C. Other Actions and Considerations

1. **With respect to liquid nicotine, should FDA require both nicotine exposure warnings (text and/or any applicable color or graphic element) and child-resistant packaging, or should only one and not the other be required? Please explain your reasoning and provide data or evidence to support your position.**

   Lane County supports the FDA in requiring both nicotine exposure warnings and child-resistant packaging for all forms of nicotine. Child-resistant packaging would help to address the risk of liquid nicotine exposure among children, while nicotine exposure warnings would raise public awareness of the dangers associated with liquid nicotine use among adults. The increased awareness among adults would also have the protective effect of improving adult storage and use patterns around children, thereby improving child safety.

2. **With respect to tobacco products other than liquid nicotine, including, but not limited to, novel tobacco products, should FDA require both nicotine exposure warnings (text and/or any applicable color or graphic element) and child-resistant packaging, or should only one and not the other be required? Please explain your reasoning and provide data or evidence to support your position.**

   Lane County supports the FDA in requiring both nicotine exposure warnings and child-resistant packaging for tobacco products other than liquid nicotine, including, but not limited to, novel tobacco products. Novel tobacco products are often flavored or scented to resemble food, drink, or candy, and therefore pose a risky attraction to infants and children.

Lane County Board of Health

Jay Bozievich — Date
Chair, Lane County Board of Commissioners

Lane County, Oregon

Patrick Luedtke, M.D. — Date
County Health Officer
Lane County Health & Human Services

References

1. Barrington-Trimis JL, Berhane K, Unger JB, Boley Cruz T, Huh J, Leventhal AM, et al. Psychosocial factors associated with adolescent electronic cigarette and cigarette use. *Pediatrics*, originally published online July 27, 2015; DOI: 10.1542/peds.2015-0639.
2. Ahmad El-Hellani, Rachel El-Hage, Rima Baalbaki, Rola Salman, Soha Talih, Alan Shihadeh, Najat A. Saliba. **Free-Base and Protonated Nicotine in Electronic Cigarette Liquids and Aerosols**. *Chemical Research in Toxicology* 2015; 150722092548000 DOI: 10.1021/acs.chemrestox.5b00107.
3. Grana R, Benowitz N, Glantz SA. E-cigarettes: A scientific review. *Circulation* 2014;129:1972-1986.
4. Center for Tobacco Control Research & Education. *9 chemicals identified so far in e-cig vapor that are on the California Prop 65 list of carcinogens and reproductive toxins*; July 20, 2013. Available at: http://www.tobacco.ucsf.edu/9□chemicals□identified□so□far□e□cig□vapor□are□california□prop□65□ listcarcinogens□and□reproductive□t.
5. Center for Tobacco Control Research & Education. *Child resistant packaging of electronic cigarette devices and refill liquid containers containing nicotine to prevent childhood poisoning*. Created June 27, 2014. Available at: https://tobacco.ucsf.edu/child-resistant-packaging-electronic-cigarette-devices-and-refill-liquid-containers-containing-nicotine
6. Hammond D. *Tobacco labelling & packaging toolkit: a guide to FCTC Article 11*. Waterloo, ON: Tobacco Labelling Resource Centre; 2009.
7. Hammond, D. Health warning messages on tobacco products: a review. Tobacco Control, originally published online May 23, 2011; DOI:10.1136/tc.2010.037630.
8. Hammond, D, Tobacco Labelling & Packaging Toolkit, A Guide to FCTC Article 11, February 2009, http://www.tobaccolabels.ca/toolkit. See also, Health Canada, The Health effects of tobacco and health warning messages on cigarette packages—Survey of adults and adults smokers: Wave 9 surveys, Prepared by Environics Research Group, January, 2005; Cragg, Ross, & Dawson, Ltd, Health warnings on cigarette and tobacco packs: Report on research to inform European standardization, December 1990; Health Education Authority, Health warnings on cigarette and tobacco packs: report on research to inform European standardization, 1990; Action on Smoking and Health, Tobacco product warnings: a survey of effectiveness, 1998; Centre for Behavioural Research in Cancer, ACCV, Health warnings and contents labelling on tobacco products,1992; Strahan, EJ, et al., "Enhancing the effectiveness of tobacco package warning labels: a social psychological perspective," Tobacco Control 11(3):183-90, 2002; AGB Spectrum Research, Ltd, Testing the positions of health warnings on cigarette packages, Prepared for Health Promotion Programme, Department of Health, New Zealand, 1987; Linthwaite, P, "Health warnings," Health Educ J 44:218-219, 1985.
9. Hammond, D, Tobacco Labelling & Packaging Toolkit, A Guide to FCTC Article 11, February 2009. See also, Cragg, Ross, & Dawson, Ltd, Health warnings on cigarette and tobacco packs: Report on research to inform European standardization, December 1990; Centre for Behavioural Research in Cancer, ACCV, Health warnings and contents labelling on tobacco products,1992; AGB Spectrum Research, Ltd, Testing the positions of health warnings on cigarette packages, Prepared for Health Promotion Programme, Department of Health, New Zealand, 1987; Linthwaite, P, "Health warnings," Health Educ J 44:218-219,1985; Environics Research Group, Ltd, Reactions to cigarette packaging formats, Prepared for the Canadian Cancer Society, Focus Canada 1999-1 March 1999; Northrup, D & Pollard, J, Plain Packaging of Cigarettes, Event Marketing to Advertise Smoking and other Tobacco Issues: A Survey of Grade Seven and Grade Nine Ontario Students, Toronto, Ontario: York University, 1995.
10. Hammond, D, *Tobacco Labelling & Packaging Toolkit, A Guide to FCTC Article 11*, February 2009. See also, CRÉATEC + Market Studies, *Effectiveness of Health Warning Messages on Cigarette Packages in Informing Less-literate Smokers, Final Report*, Prepared for Communications Canada, December 2003; Millar, WJ, "Reaching smokers with lower educational attainment," *Health Rep* 8:11-9, 1996; Siahpush, M, et al., "Socioeconomic and country variations in knowledge of health risks of tobacco smoking and toxic constituents of smoke: Results from the 2002 International Tobacco Control Policy Evaluation Survey," *Tobacco Control* 15(Suppl III): iii65–iii70, 2006; Liefeld, JP, *The Relative Importance of the Size, Content and Pictures on Cigarette Package Warning Messages*, Department of Consumer Studies, University of Guelph, Prepared for Health Canada, 1999; O'Hegarty, M, et al., "Reactions of young adult smokers to warning labels on cigarette packages," *Am J Prev Med* 30(6):467-73, June 2006; Elliott & Shanahan (E&S) Research, *Developmental Research for New Australian Health Warnings on Tobacco Products Stage 2*, Prepared for The Australian Population Health Division Department of Health and Ageing. Commonwealth of Australia, August 2003; Corporate Research Associates, Creative Concept Testing for Health Warning Messages. Prepared for Health Canada, 2005; Les Etudes de Marche Createc, *Final Report: Qualitative testing of health warnings messages,* Prepared for the Tobacco Control Programme Health Canada, June 2006; BRC Marketing & Social Research, *Smoking health warnings Stage 1: The effectiveness of different (pictorial) health warnings in helping people consider their smoking-related behavior,* Prepared for the New Zealand Ministry of Health, May 2004; BRC Marketing & Social Research, *Smoking health warnings Stage 2: Optimising smoking health warnings-text graphics, size, and*

colour testing, Prepared for the New Zealand Ministry of Health, August 2004; Liefeld, JP, *The Relative Importance of the Size, Content and Pictures on Cigarette Package Warning Messages*, Department of Consumer Studies, University of Guelph, Prepared for Health Canada, 1990; Environics Research Group, Testing *New Health Warning Messages for Cigarette packages: A Summary of Three Phases of Focus Group Research: Final Report,* Prepared for Health Canada, 2000; Elliott & Shanahan (E&S) Research, *Developmental Research for New Australian Health Warnings on Tobacco Products Stage 2*, Prepared for The Australian Population Health Division Department of Health and Ageing, Commonwealth of Australia, August 2003; Clemenger BBDO, *Marketing inputs to assist the development of health warnings for tobacco packaging,* Report to the Ministry of Health: Review of the Smoke-free Environments Regulations, 2004; Thrasher, JF, et al., "Smokers' reactions to cigarette package warnings with graphic imagery and with only text: A comparison between Mexico and Canada," *Salud Publica Mex* 49(Suppl 2):S233-40,2007; Vardavas, CI,et al., "Adolescents perceived effectiveness of the proposed European graphic tobacco warning labels," *European Journal of Public Health* 19(2):212-7, 2009. Kees, J, et al., "Tests of Graphic Visuals and Cigarette Package Warning Combinations: Implications for the Framework Convention on Tobacco Control," *Journal of Public Policy & Marketing* 25(2):212-223, Fall 2006.

11. Hammond, D, et al., "Graphic Canadian warning labels and adverse outcomes: evidence from Canadian smokers," *American Journal of Public Health* 94(8), 2004. Hammond, D, *Tobacco Labelling & Packaging Toolkit, A Guide to FCTC Article 11*, February 2009. See also, Environics Research Group, *Testing New Health Warning Messages for Cigarette packages: A Summary of Three Phases of Focus Group Research: Final Report*, Prepared for Health Canada, 2000; Thrasher JF, et al, "Estimating the impact of pictorial health warnings and "plain" cigarette packaging: Evidence from experimental auctions among adult smokers in the United States," *Health Policy*, 2011. Les Etudes de Marche Createc, *Final Report: Qualitative testing of health warnings messages,* Prepared for the Tobacco Control Programme Health Canada, June 2006; Goodall, C & Appiah, O, "Adolescents' perceptions of Canadian cigarette package warning labels: Investigating the effects of message framing," *Health Communication* 23, 2008; Sobani, Z, et al., "Graphic tobacco health warnings: which genre to choose?" *Int J Tuberc Lung Dis* 14(3), 2010; Kees, J, et al., "Understanding How Graphic Pictorial Warnings work on Cigarette Packaging," *Journal of Public Policy & Marketing* 29(2), Fall 2010.
12. **Woolf A, Burkhart K, Caraccio T, Litovitz T.** Childhood poisoning involving transdermal nicotine patches. **Pediatrics.** 1997 May;99(5):E4.
13. Scollo MM, Winstanley, MH. Tobacco in Australia: Facts and issues. 4th edition. Melbourne: Cancer Council Victoria; 2012.