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Commentary

Withholding differential risk information on legal consumer nicotine/tobacco products: The public health ethics of health information quarantines

Lynn.T. Kozlowski [a,*], David Sweanor [b]

[a] University at Buffalo, State University of New York, School of Public Health and Health Professions, Professor, Department of Community Health and Health Behavior, Buffalo, NY, USA
[b] Adjunct Professor of Law and Member of the Centre for Health Law, Policy and Ethics, University of Ottawa, Ottawa, Canada

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ABSTRACT

The United States provides an example of a country with (a) legal tobacco/nicotine products (e.g., snus, other smokeless tobacco, cigarettes) differing greatly in risks to health and (b) respected health information websites that continue to omit or provide incorrect differential risk information. Concern for the principles of individual rights, health literacy, and personal autonomy (making decisions for oneself), which are key principles of public health ethics, has been countered by utilitarian arguments for the use of misleading or limited information to protect public health overall. We argue that omitting key health relevant information for current or prospective consumers represents a kind of quarantine of health-relevant information. As with disease quarantines, the coercive effects of quarantining information on differential risks need to be justified, not merely by fears of net negative public health effects, but by convincing evidence that such measures are actually warranted, that public health overall is in imminent danger and that the danger is sufficient to override principles of individual autonomy. Omitting such health-relevant information for consumers of such products effectively blindfolds them and impairs their making informed personal choices. Moral psychological issues that treat all tobacco/nicotine products similarly may also be influencing the reluctance to inform on differential risks. In countries where tobacco/nicotine products are legally sold and also differ greatly in disease risks compared to cigarettes (e.g., smokeless tobacco and vape), science-based, comprehensible, and actionable health information (consistent with health literacy principles) on differential risks should be available and only reconsidered if it is established that this information is causing losses to population health overall.

This commentary focuses on the example of smokeless tobacco and cigarettes in the United States. It arises out of revisiting a report on information on major health websites in 2003 (Kozlowski & O'Connor, 2003) which found considerable misinformation or disinformation on relative risks on these sites. Improvements have been identified, but concerns continue about the lack of information on significant differential health risks between cigarettes and smokeless tobacco. The ethical arguments presented can be applied to any country where tobacco/nicotine products (including vape or electronic cigarettes) with differential health risks are sold and agencies and organizations can provide health information related to these products.

Differential harm from smokeless tobacco products and cigarettes

The American public is unaware of dramatic differential harms from different legal tobacco/nicotine products (Kiviniemi & Kozlowski, 2015). Conflicting headlines and media reports contribute to the compromise of public awareness (Berman, 2008; Eversman, 2015; Liu et al., 2015). The National Cancer Institutes (NCI) national survey on health information evaluated public beliefs about how smokeless tobacco (SLT) risks compared to cigarette risks and asked: "In your opinion, do you think that some smokeless tobacco products, such as chewing tobacco, snus

* Corresponding author at: Department of Community Health and Health Behavior, School of Public Health and Health Professions, University at Buffalo, 323 Kimball Tower, 3435 Main Street, Buffalo, NY 14214-8028, USA.
Tel.: +1 716 829 6770; fax: +1 716 829 6040.
E-mail address: lk22@buffalo.edu (Lynn.T. Kozlowski).

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and snuff are less harmful to a person's health than cigarettes?" Only 9.4% of the public answered "yes" (Kiviniemi & Kozlowski, 2015). This small proportion of people aware of any difference in risk is of course not evidence that they comprehend the magnitude of the risk differential, which would be necessary to exercise personal autonomy.

The Surgeon-General has concluded that combustible tobacco products are by far of greatest concern for public health (United States Public Health Service. Office of the Surgeon General, 2014). Though not safe, there is no scientific doubt that manufactured smokeless tobacco (SLT) products in the U.S. (and notably, low-nitrosamine Swedish snus) are dramatically less dangerous than cigarettes to life-long users of each product (Benowitz, 2011; Levy et al., 2004; Piano et al., 2010; Scientific Committee on Emerging and Newly Identified Health Risks, 2008; Stratton, 2001). In the U.S., the essentially complete avoidance of lung cancer risks and other respiratory disease risks (Scientific Committee on Emerging and Newly Identified Health Risks, 2008) alone would reduce mortality by 54.8% (Center for Disease Control and Prevention, 2015) The American Heart Association review panel concluded: "Data from international, European, and US studies overwhelmingly demonstrate that compared with ST users, active smokers are at much greater risk for CV [Cardio-vascular] morbidity and mortality and have shorter life spans." A European review judged that the cardio-vascular disease risk reduction is at least 50% compared to smoking (Scientific Committee on Emerging and Newly Identified Health Risks, 2008). Overall estimates of risk reduction from snus versus cigarettes have been 90% or more (Lee, 2013; Levy et al., 2004).

Past and current health website deficiencies

In 2003 (Kozlowski & O'Connor, 2003) the information on the Centers for Disease Control and Prevention (CDC) and the Substance Abuse and Mental Health Services Administration (SAMHSA) web-sites was assessed on the popular question of whether SLT was safer than cigarettes. These sites had erroneously informed that SLT was as dangerous as cigarettes. For organizations committed to health information quality (Office of Management and Budget, 2002), this was considered an ethical lapse and examples of health misinformation or disinformation.

In November 2015, inspection of major health information web-sites of CDC (Centers for Disease Control and Prevention, 2015). SAMHSA (Substance Abuse and Mental Health Services Administration, 2015), American Cancer Society [ACS] (American Cancer Society, 2015), NCI (National Cancer Institute, 2015) and the Mayo Clinic (Mayo Clinic, 2015)) found three types of examples of information on SLT, but no to modest efforts to inform consumers of the significantly lower risks compared to cigarettes for lifelong users (see Table 1.) The Mayo Clinic perpetuates the error found in 2003 with the headline: "Chewing tobacco: Not safer than smoking." ("Chewing tobacco" refers to all SLT.) CDC, SAMHSA, and NCI provide no cigarette-comparative risk information that might help correct public misunderstandings. ACS provides some comparative information: "Smokeless tobacco products are less lethal than cigarettes: On average, they kill fewer people than cigarettes." Consumers might also value learning, and individual rights and personal autonomy require they be informed of, the considerable magnitude of difference in harms.

Information on comparative risks is commonplace—except for tobacco/nicotine

If science learned that one type of alcoholic beverage caused 3 in 5 regular users to die prematurely, losing 10 years of life (Jha et al., 2013), while another alcoholic beverage caused 95% or even 9.5% fewer premature deaths, consumers would want to know which legal product was which. (With alcohol the especially dangerous item would be banned, but assume that, as with current Food and Drug Administration (FDA) tobacco law, this is impossible.) It would be scandalous, even criminal, to keep such facts from consumers. Yet, such facts are being kept from adult consumers of legal tobacco/nicotine products (Kiviniemi & Kozlowski, 2015) either by not informing or actively misinforming consumers (Kozlowski & O'Connor, 2003). It is as if tobacco consumers were blindfolded and not allowed to see dramatic differences in harm from different products.

In the U.S. there is a National Action Plan to improve health literacy (U.S. Department of Health and Human Services, 2010) and all Federal agencies are required to ensure the "quality, objectivity, utility, and integrity of information disseminated" (Office of Management and Budget, 2002). "Health literacy is the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" (U.S. Department of Health and Human Services, 2010) The importance of informing consumers about meaningful differential risks of various products (e.g., crash worthiness of cars) and the direct risks of unsafe products (e.g., over-the-counter and prescription drugs) is widely accepted in consumer protection laws and in product liability litigation, and it is viewed as negligent to fail to do so (Cornell University Law School, 2015). However, informing consumers of differential harms from various tobacco/nicotine products has been controversial, out of fear that this personal health information may have net negative effects on population health as a whole (Eversman, 2015; Gray & Henningfield, 2006; Hatsukami, Lemmonds, & Tomar, 2004; Maziak, 2014; McKenna, Pechacek, & Stroup, 2003; Tomar, Fox, & Severson, 2009; Watson & Forshaw, 2015).

The FDA is doing little to strip off the blindfold, even though the Director of its Center for Tobacco Products has acknowledged a significant continuum of risk (Zeller, 2012) and the differences in risks are dramatic (Nutt et al., 2014). FDA has a mandate to do public education on tobacco; however, FDA law fundamentally protects cigarettes and smokeless tobacco for adults and forbids banning. Marketing is allowed, and the law discourages requiring any product changes that could encourage contraband markets.

Table 1
Summary of comparative information on the harms from cigarettes (Cig) versus smokeless tobacco (SLT) from current notable institutions.

	Message type	Site	Lung cancer	Respiratory disease	CVD	Health literacy quality
1	SLT = Cig Harm	Mayo (Mayo Clinic, 2015)*	No info	No info	No info	Falsehood
2	SLT Harm Only	CDC (Centers for Disease Control and Prevention, 2015) NCI (National Cancer Institute, 2015), SAMHSA (Substance Abuse and Mental Health Services Administration, 2015)	No info	No info	No info	Correct on SLT harms; no comparison with smoking
3	SLT Harm less lethal	ACS (American Cancer Society, 2015)	No info	No info	No info	Correct on SLT, Limited comparisons with smoking

* The Mayo Clinic website changed on April 2, 2016, substituting a "not a safe product" heading for the previous "not safer than cigarettes" heading.

(Altria which controls over half of the national cigarette market actively supported this law (Wilson, 2009).) FDA law even has a unique provision for tobacco (United States Code, 2009) which forbids marketing by manufacturers of any reduced-harm product information unless it has been proven *before marketing that such marketing will not have an adverse effect on population health*, a near-impossible task, a barrier that no product has yet surmounted, and one not imposed on other FDA-regulated product categories. FDA, despite its mandate to engage in public education, has to date transferred the responsibility for providing accurate life-critical consumer product information to the commercial marketing of tobacco companies. But such a high regulatory standard, likely combined with cigarette-focused companies benefiting from not surmounting it, contributes to smokers being ill-informed about product risks. When the most deadly "disease" (smoking) is protected by FDA, it is as if needle-exchange programs had to prove no negative public health effects before being implemented—while heroin given via dirty syringes was sold over-the-counter.

It is interesting to speculate how the FDA and health authorities might treat a new pill that dramatically reduced the risk of lung cancer. We think the focus would be on allowing the company to market this pill, with relatively little concern about the possible negative effects if smokers were to reduce their desire to stop smoking because of the availability of the pill and perhaps experience continued risks of other respiratory or cardiovascular disease. There would likely not be as much attention to possible net effects on population health.

Large vs. negligible harm reduction

Public health concerns arising from reduced-risk claims (Stratton, 2001) probably arose to try to prevent repeating the public health tragedy of "low tar" cigarettes which encouraged smokers to continue smoking and yet had negligible, if any, effects on reducing smoking-caused diseases (National Cancer Institute, 2001). *Again: Lower-tar cigarettes did not significantly reduce the harms of smoking!* Public health losses were caused by consumers being misled in a way that resulted in more dangerous behaviors – more people smoking than would have otherwise been the case. Ironically, the same manner of deleterious effect could flow from allowing consumers to overestimate the risks of truly less hazardous products, causing them to avoid switching to a product that they do not appreciate is much less hazardous. The error of presenting products with no meaningful risk reduction as if they were safer cannot be redressed by committing the equally life-threatening error of presenting products with large risk reductions as if they are not safer or by concealing this information.

Unjustified health information 'quarantine'

Public health ethics permits suppression of individual rights to protect public health, as with required vaccinations and quarantines (Cetron & Landwirth, 2005; Kass, 2001, 2004). But these exceptions to the rule on individual autonomy demand strong justification, not just suspicions, even plausible ones, that it could be warranted. Ethical analysis of public health decision-making on quarantines emphasizes the principles of proportionality and effectiveness. It is worth quoting Kass (2001) because it illustrates both the issues and the complexity of the current predicament:

> Programs that are coercive should be kept to a minimum, should never be implemented when a less restrictive program would achieve comparable goals, and **should be implemented only in the face of clear public health need and good data demonstrating effectiveness.** Nonetheless, we are a pluralistic society, including with regard to our notions of ethics. Different states and communities will decide differently which public health activities are appropriate and which are overly burdensome. [emphasis added]

Part one of Kass's point is that coercive actions need prior justification from a *clear public health need* and *good data demonstrating effectiveness*. For tobacco control, (a) the most urgent public health need is to reduce the use of combustible tobacco, especially cigarettes (United States Public Health Service. Office of the Surgeon General, 2014) and (b) good data is lacking to demonstrate that restricting accurate information or engaging in active misinformation on reduced-harm products has any good effects on population health. Similarly, U.S. rules on information quality do allow standards to be "waived temporarily" only under "urgent situations (e.g., imminent threats to public health or homeland security)" (p. 8485) (Office of Management and Budget, 2002). It is simply preposterous to think the current evidence base demonstrates there is an "imminent threat" to public health in this instance.

But part two of Kass's point is that community standards also influence the appropriateness of public health activities. The demonization of tobacco/nicotine products and the tobacco industry may have distorted public health principles by *acting as if all tobacco products should be banned* (Proctor, 2013). A moral outrage has characterized views on tobacco which has been much greater than for other unsafe, legal and even illicit consumer products (MacCoun, 2013). Harm reduction principles have been readily embraced for many decidedly unsafe commercial products (cars, pharmaceuticals, alcohol), and for behaviors often illicit or morally objectionable to others, yet cigarettes and tobacco have been treated quite differently.

Ethical analysis, moral psychology, and anti-vice inclinations

For many people, when cigarettes were judged as (1) the largest single cause of preventable death and disability, (2) lethal when used as intended by manufacturers, and estimated to be more deadly than the next several most dangerous activities combined, they crossed a line (American Cancer Society, 1987; Warner et al., 1986). When the behavior of cigarette companies so infuriated the public, these companies became seen as evil, and this encouraged an absolutist, anti-vice response (Berridge, 2013; Courtwright, 2012; McCambridge, 2015). (The matter of the predations of tobacco industry marketing is very distinct from respected health information websites trying to improve consumers' knowledge and should not be confused.) Detailed ethical analyses of tobacco/nicotine harm reduction are available (Chapman & Daube, 2015; Hall & Forlini, 2015; Kozlowski, 2002, 2015b; Kozlowski & Edwards, 2005; Kozlowski & O'Connor, 2003; McCambridge, 2015; Royal College of Physicians, 2007; Savitz, Meyer, Tanzer, Mirvish, & Lewin, 2006). They have employed standard issues like beneficence, non-maleficence, justice, and autonomy. In an area charged by views of vice and improper behavior, it important to consider moral psychological perspectives that point to strong moral emotional reactions to violations of a sense of purity, respect for authority, and a concern about community standards (Haidt, 2007). Such violations can trigger emotionally charged moral reactions (disgust and contempt) for tobacco use and even to the use of much less-harmful tobacco/nicotine products (Alderman, Dollar, & Kozlowski, 2010; Kozlowski, 2013, 2015b).

Utilitarian principles and evidence for coercive actions

In a CDC response (McKenna et al., 2003) to the 2003 critique (Kozlowski & O'Connor, 2003) of misleading information (indicating that SLT was not safer than cigarettes), the authors, in keeping

with arguments from the Institute of Medicine review (Stratton, 2001), assert several ways in which SLT could cause public health losses:

> Even if some smokers who switch to SLT do reduce their individual risk, it is plausible that overall population health risk would increase if SLT were promoted as a potential reduced-exposure product. This conclusion assumes that (a) some smokers who would have otherwise quit using tobacco would switch to SLT or continue to smoke and use SLT; (b) the number of lifelong SLT users would rise as a result of increased youth SLT initiation; (c) the number of smokers would rise as a result of increased youth SLT initiation with subsequent switching to cigarette use; and/or (d) some former smokers would relapse, believing SLT a less hazardous way to consume tobacco. (p. 194)

Theoretical concerns are not enough, however, no matter how plausible or how many, to justify information quarantine. Both (a) *evidence* of a problem and (b) *evidence* that the deception/evasion is important in dealing with the problem are needed. The rights of SLT users to have information that might prevent their sometimes smoking or even switching to cigarettes should not be so readily waived. Accurate science-based, comprehensible, and actionable health information on comparative risk is also not strictly a "promotion" of reduced-risk products as done by a manufacturer, rather it is a contribution to health literacy that in the context of systematic tobacco control efforts might "plausibly" even produce public health gains. Anyone, no matter their current use of tobacco or nicotine products, could value being knowledgeable about differential product risks for themselves or their loved ones.

"Gateway effects" whereby SLT *causes* later smoking has been a topic of major interest in tobacco control and provides an example of the small magnitude of confirmed adverse effects as well as failures to find effects (e.g., Kozlowski, O'Connor, Quinio Edwards, & Flaherty, 2004; O'Connor, Flaherty, Quinio Edwards, & Kozlowski, 2003; Tomar et al., 2009). The political power of gateway fears is greater than their scientific usefulness (Bell & Keane, 2014; Kleinig, 2015; Phillips, 2015). For many drug researchers, causal gateway models have been abandoned in favor of an appreciation that circumstances influence which drug products youth start with (Degenhardt et al., 2010) and that individual and contextual characteristics make some individuals at higher risk (and others at lower risks) of using drug products (Vanyukov & Ridenour, 2012). Certainly, a mere unproven hypothesis does not provide an ethical basis for information quarantine.

A recent review of longitudinal research shows that overall non-smoking adults (including SLT users) are unlikely to become cigarette smokers (Tam, Day, Rostron, & Apelberg, 2015). A study in military recruits indicated the greatest risk of non-smoking SLT initiators becoming smokers (Haddock et al., 2001), but it is noted that context may reduce generalizability (Tam et al., 2015). Even then, the *minority* (about 27%) of SLT tobacco users turned to smoking, compared to about 13% for those who had not used SLT (Haddock et al., 2001). A long-term longitudinal study has found great stability in use of SLT or cigarettes and that beliefs about the risks of these products influence use (Macy, Li, Xun, Presson, & Chassin, 2015). National patterns of e-cigarette use (Delnevo et al., 2015) or smokeless tobacco use (Tomar, Alpert, & Connolly, 2010) do not give evidence of net public health losses in the area of tobacco use and shifts to cigarettes that might help justify a quarantine of information on reduced risk products. Indeed, it seems simply absurd to justify not giving consumers sufficient information to make informed decisions based on the view that previously ill-informed consumers may have made poor decisions or that well-informed consumers might make the "wrong" decision. Sweden provides an example of finding *no evidence* of any noteworthy causal gateway effects from snus to cigarettes, despite a close look for it (Foulds, Ramstrom, Burke, & Fagerstrom, 2003; Scientific Committee on Emerging and Newly Identified Health Risks, 2008). Although the U.S. might be different (Tomar et al., 2009), evidence from Sweden should be weighed more heavily than hypotheses that lack an ethical basis and a persuasive evidence base. Even if a smoker switching to SLT later in life would have smaller effects on disease reductions, it is clear that those who would stop smoking by 30 or 40 are likely to see dramatic reductions in smoking-caused disease to near never-smoking levels (Jha et al., 2013). Given policy options available to nudge tobacco use behavior (such as differential taxation, marketing and information) (Jha & Chaloupka, 1999; Kozlowski, 2007, 2015a, 2016), a more reasonable approach to any apprehension of risk should be based on the application rather than the denial of the principle of health literacy. Research on snus use in Norway has found that providing accurate risk estimates to smokers can result in increased quit-rates for smoking (Lund & Lund, 2014; Lund, 2012).

Care for autonomy and individual rights

If accurate information on relative risks of various products helps even a few users of cigarettes to move from or stay away from cigarettes, it is preferable to a context of providing no information, misinformation, or disinformation to consumers of these products (Kiviniemi & Kozlowski, 2015; Kozlowski, O'Connor, & Edwards, 2003). An ethical basis for public health communications to establish health literacy, one focused on individual autonomy and accurate information (which FDA could help determine), should be required (Office of Management and Budget, 2002). Denial of information to consumers could have similar effects as the historic efforts of cigarette companies to mislead smokers about disease risks and to fight against health information on cigarette advertisements and packaging. While the industry may have been motivated by profits and the health agencies had different motivations, the negative effects for individual users could be the same. Evidence is growing that snus can aid smoking cessation (Hatsukami, Severson, et al., 2015). Use of lower-harm products (including vape) may not be for everyone, and the ability of these to supplant smoking remains to be shaped and delineated. If the user does not enjoy the product, it is unlikely to be used for long (Kozlowski, 1982; Kozlowski, Heatherton, Frecker, & Nolte, 1989; Saddleson et al., 2016). Personal satisfaction with any product is important (Hatsukami, Vogel, Severson, Jensen, & O'Connor, 2015). But the blindfolding of consumers delays such transitions and impedes efforts to develop products that could more effectively replace cigarettes.

For a very much lower-risk product (Nutt et al., 2014), it could take an impossible increase in users to match public health harm of cigarettes (Kozlowski, Strasser, Giovino, Erickson, & Terza, 2001). For small reductions in risk (e.g., 10%), negative population health consequences are far likelier. How many recreational users of snus (Hatsukami, Severson, et al., 2015) or vape would avoid cigarettes completely could be influenced by accurate information and appropriate marketing. Until differential marketing according to risks is actually implemented (Branston & Sweanor, 2016; Chaloupka, Sweanor, & Warner, 2015; Kozlowski, 2007), it is hard to know the impact that products like SLT or vaping could have on cigarette use. But it is unethical as well as lacking a scientific basis to maintain that there is so little reason to believe that consumers would respond to adequate information on differential risks that there is no point in even considering removing their blindfold.

Current FDA tobacco rules and educational practices on prominent web-sites represent a swamp of precaution that contributes to preventing broader awareness of products that

are known to be dramatically safer than cigarettes. Efforts should be made to educate the public about the nature of risks from different classes or types of tobacco products (Biener, Bogen, & Connolly, 2007; Biener, Nyman, Stepanov, & Hatsukami, 2014; Kiviniemi & Kozlowski, 2015) and how burning and inhalation makes a difference (Strasser et al., 2011). Simple but effective graphic tools like traffic-light systems can be employed (Strasser et al., 2011). A growing evidence base on e-cigarettes indicates that they too are dramatically less dangerous than cigarettes (Hajek, Etter, Benowitz, Eissenberg, & McRobbie, 2014; McNeill, Calder, Hitchman, Hajek, & McRobbie, 2015) (As with vape, long-term epidemiology of the new imaginary wonder pill for lung cancer would also be a work in progress; since the 1970s, 35 prescription drugs have been removed from the market (ProCon.org, 2014).) So once again, a mere hypothesis of a potential problem, one lacking an evidentiary basis, is not sufficient to justify blindfolding consumers.

Complexities of ethical analysis of public health police powers

Coercive measures on behalf of public health are also called police powers. Quarantines to prevent the spread of disease are not the only example of public health police powers. The principles of autonomy, privacy, liberty and personal property can conflict with actions to try to protect public health. We have emphasized issues arising from public health efforts to prevent net harm to population health. A classic work on public health law (Gostin & Wiley, 2016) does recognize that these questions must always be posed:

> ... whether a coercive intervention truly reduces aggregate health risks and what, if any, less-intrusive interventions might reduce those risks as well or better? Respect for the rights of individuals and fairness toward groups of all races, religions, and cultures remain at the heart of public health. (p. 11)

But it should be admitted that ethical arguments have been based on principles other than aggregate harm to the population. Some ethicists prefer to use paternalism (or parentalism) to justify protecting even mentally competent, adult citizens from themselves 'for their own good.' See Gostin and Wiley (2016) for a discussion of this and other perspectives. In contrast, a focus on the importance of liberty even in the face of utilitarian costs opposes paternalism (e.g. Berlin, Hardy, & Harris, 2002). We prefer to give strong emphasis on the principles of personal autonomy and individual rights while not ignoring utilitarian issues which is sometimes called a 'rule-utilitarian position.' Also, although we have focused on issues pertaining to adult consumers of legal products, we see no case for keeping comprehensible health information about products away from those who may not be legally able to purchase these products and do not know how that could be done if made available to adults.

Summary

Table 2 outlines the main ethical and moral psychological issues discussed. Concerns for some adverse public health effects of harm reduction products such as SLT and vape are reasonable and worth trying to minimize, but there is no current evidence that such products actually represent *an imminent danger to public health overall* and that withholding information about relative risks is an effective way to promote overall public health. Efforts to discourage the use of tobacco/nicotine products need not be reduced, but should be done in a harm-proportionate way. Telling consumers that all product options are as bad as cigarettes is untrue and almost certainly as deadly for users as telling at-risk populations that condom use affords no protection. Giving accurate information does not guarantee that a problem will be solved, but it stands the ethical rules on their head to not value health literacy and information quality (Office of Management and Budget, 2002). That reduced-harm products are not absolutely 'safe' and more dangerous than using no tobacco/nicotine product does not justify keeping potential consumers of legal products ignorant about this information any more than such arguments would for any other product or activity.

Table 2
Key ethical perspectives on providing accurate health information to consumers of unsafe legal consumer products.

1	Health Literacy and respect for autonomy are critical
2	Utilitarian principles (greatest good for the greatest number) support concern about science-based, comprehensible, and actionable information that is shown to harm public health
3	To be ethical, coercive measures (e.g., information quarantine) require more than plausible concerns, but actual *prior evidence* that the measures are *proportionate and effective* in protecting public health
4	Moral psychological reactions (disgust and contempt) arising from the views of and nature of tobacco products and the behavior of industry violate 'community standards,' 'proper respect for authority' and 'a sense of purity,' and promote acting as if all tobacco/nicotine *should be* banned
5	Omitting accurate health information that might guide behavior and decisions of *any* (even a few) users of legal products is inconsistent with health literacy and respect for autonomy
6	To achieve utilitarian goals, other product differentiating tobacco control/marketing methods should be exhausted before deceptive or evasive health information are employed—if they ever are included as an option

For evidence-based health organizations to provide accurate information on the relative harms of tobacco/nicotine products does not even carry with it any concerns that apply to manufacturers embedding relative-risk information in lifestyle advertising designed to recruit customers. The straight-forward principles of harm reduction should be as uncontroversial for tobacco products as they are for alcohol, cars, air travel, children's clothing, sexual practices, electrical goods and other goods and activities – until such time as there is compelling, proportionate evidence of imminent danger to public health overall that would ethically justify promoting health illiteracy with respect to these legal products. Even then, some ethicists would never support deceptive information as an appropriate public health option (Bok, 1978) and the risk of loss to credibility would be earnestly avoided.

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References

Alderman, J., Dollar, K. M., & Kozlowski, L. T. (2010). Commentary: Understanding the origins of anger, contempt, and disgust in public health policy disputes: Applying moral psychology to harm reduction debates. *Journal of Public Health Policy, 31*, 1–16.

American Cancer Society (1987). *Smoke signals: The smoking control media handbook*. American Cancer Society.

American Cancer Society (2015). *Smokeless tobacco*. Retrieved from http://www.cancer.org/cancer/cancercauses/tobaccocancer/smokeless-tobacco

Bell, K., & Keane, H. (2014). All gates lead to smoking: The 'gateway theory', e-cigarettes and the remaking of nicotine. *Social Science and Medicine, 119*, 45–52.

Benowitz, N. L. (2011). Smokeless tobacco as a nicotine delivery device: Harm or harm reduction? *Clinical Pharmacology and Therapeutics, 90*, 491–493.

Berlin, I., Hardy, H., & Harris, I. (2002). *Liberty: Incorporating four essays on liberty*. Oxford: Oxford University Press.

Berman, M. L. (2008). Tobacco litigation without the smoke? Cigarette companies in the smokeless tobacco industry. *Journal of Health Care Law & Policy, 11*, 7–55.

Berridge, V. (2013). *Demons: Our changing attitudes to alcohol, tobacco, & drugs* (1st ed.). Oxford, United Kingdom: Oxford University Press.

Biener, L., Bogen, K., & Connolly, G. (2007). Impact of corrective health information on consumers' perceptions of "reduced exposure" tobacco products. *Tobacco Control, 16*, 306–311.

Biener, L., Nyman, A. L., Stepanov, I., & Hatsukami, D. (2014). Public education about the relative harm of tobacco products: An intervention for tobacco control professionals. *Tobacco Control, 23*, 385–388.

Bok, S. (1978). *Lying: Moral choice in public and private life*. New York: Pantheon Books.

Branston, J. R., & Sweanor, D. (2016). Big tobacco, E-cigarettes, and a road to the smoking endgame. *International Journal on Drug Policy, 29*, 14–18.

Center for Disease Control and Prevention (2015). *Tobacco-Related Mortality*. Retrieved from http://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/tobacco_related_mortality/

Centers for Disease Control and Prevention (2015). *Smokeless tobacco: Health effects*. Retrieved from http://www.cdc.gov/tobacco/data_statistics/fact_sheets/smokeless/health_effects/index.htm

Cetron, M., & Landwirth, J. (2005). Public health and ethical considerations in planning for quarantine. *The Yale Journal of Biology and Medicine, 78*, 329–334.

Chaloupka, F. J., Sweanor, D., & Warner, K. E. (2015). Differential taxes for differential risks – Toward reduced harm from nicotine-yielding products. *New England Journal of Medicine, 373*, 594–597.

Chapman, S., & Daube, M. (2015). Ethical imperatives assuming ENDS effectiveness and safety are fragile. *Addiction, 110*, 1068–1069.

Cornell University Law School (2015). *Negligence*. Retrieved from https://www.law.cornell.edu/wex/negligence

Courtwright, D. T. (2012). *A Short History of Drug Policy or Why We Make War on Some Drugs but not on Others*.

Degenhardt, L., Dierker, L., Chiu, W. T., Medina-Mora, M. E., Neumark, Y., Sampson, N., et al. (2010). Evaluating the drug use "gateway" theory using cross-national data: Consistency and associations of the order of initiation of drug use among participants in the WHO World Mental Health Surveys. *Drug and Alcohol Dependence, 108*, 84–97.

Delnevo, C. D., Giovenco, D. P., Steinberg, M. B., Villanti, A. C., Pearson, J. L., Niaura, R. S., et al. (2015). Patterns of electronic cigarette use among adults in the United States. *Nicotine & Tobacco Research*.

Eversman, M. H. (2015). Harm reduction in U.S. tobacco control: Constructions in textual news media. *International Journal on Drug Policy, 26*, 575–582.

Foulds, J., Ramstrom, L., Burke, M., & Fagerstrom, K. (2003). Effect of smokeless tobacco (snus) on smoking and public health in Sweden. *Tobacco Control, 12*, 349–359.

Gostin, L. O., & Wiley, L. F. (2016). *Public health law: Power, duty, restraint* (3rd ed.). University of California Press.

Gray, N., & Henningfield, J. (2006). Dissent over harm reduction for tobacco. *Lancet, 368*, 899–901.

Haddock, C. K., Weg, M. V., DeBon, M., Klesges, R. C., Talcott, G. W., Lando, H., et al. (2001). Evidence that smokeless tobacco use is a gateway for smoking initiation in young adult males. *Preventive Medicine, 32*, 262–267.

Haidt, J. (2007). The new synthesis in moral psychology. *Science, 316*, 998–1002.

Hajek, P., Etter, J. F., Benowitz, N., Eissenberg, T., & McRobbie, H. (2014). Electronic cigarettes: Review of use, content, safety, effects on smokers and potential for harm and benefit. *Addiction*.

Hall, W. G. C., & Forlini, C. (2015). Ethical issues raised by a ban on the sale of electronic nicotine devices. *Addiction*.

Hatsukami, D. K., Lemmonds, C., & Tomar, S. L. (2004). Smokeless tobacco use: Harm reduction or induction approach? *Preventive Medicine, 38*, 309–317.

Hatsukami, D. K., Severson, H., Anderson, A., Vogel, R. I., Jensen, J., Broadbent, B., et al. (2015). Randomised clinical trial of snus versus medicinal nicotine among smokers interested in product switching. *Tobacco Control*.

Hatsukami, D. K., Vogel, R. I., Severson, H. H., Jensen, J. A., & O'Connor, R. J. (2015). Perceived health risks of snus and medicinal nicotine products. *Nicotine & Tobacco Research*.

Jha, P., & Chaloupka, F. J. (1999). *Curbing the epidemic: Governments and the economics of tobacco control*. World Bank Publications.

Jha, P., Ramasundarahettige, C., Landsman, V., Rostron, B., Thun, M., Anderson, R. N., et al. (2013). 21st-century hazards of smoking and benefits of cessation in the United States. *New England Journal of Medicine, 368*, 341–350.

Kass, N. E. (2001). An ethics framework for public health. *American Journal of Public Health, 91*, 1776–1782.

Kass, N. E. (2004). Public health ethics from foundations and frameworks to justice and global public health. *Journal of Law, Medicine & Ethics, 32*, 232–242.

Kiviniemi, M. T., & Kozlowski, L. T. (2015). Deficiencies in public understanding about tobacco harm reduction: Results from a United States national survey. *Harm Reduction Journal, 12*, 21.

Kleinig, J. (2015). Ready for retirement: The gateway drug hypothesis. *Substance Use and Misuse, 50*, 971–975.

Kozlowski, L. (2016). A policy experiment is worth a million lives. *Issues in science and technology, 32*(2), 20–23. Winter 2016.

Kozlowski, L., Strasser, A., Giovino, G., Erickson, P., & Terza, J. (2001). Applying the risk/use equilibrium: Use medicinal nicotine now for harm reduction. *Tobacco Control, 10*, 201.

Kozlowski, L. T. (1982). The determinants of tobacco use: Cigarette smoking in the context of other forms of tobacco use. *Canadian Journal of Public Health,* Revue Canadienne de Santé Publique*73*, 236–241.

Kozlowski, L. T. (2002). Harm reduction, public health, and human rights: Smokers have a right to be informed of significant harm reduction options. *Nicotine & Tobacco Research, 4*, S55–S60.

Kozlowski, L. T. (2007). Effect of smokeless tobacco product marketing and use on population harm from tobacco use: Policy perspective for tobacco-risk reduction. *American Journal of Preventive Medicine, 33*, S379–S386.

Kozlowski, L. T. (2013). Ending versus controlling versus employing addiction in the tobacco-caused disease endgame: Moral psychological perspectives. *Tobacco Control, 22*, i31–i32.

Kozlowski, L. T. (2015a). Prospects for a nicotine-reduction strategy in the cigarette endgame: Alternative tobacco harm reduction scenarios. *International Journal on Drug Policy*.

Kozlowski, L. T. (2015b). The truncation of moral reasoning on harm reduction by individuals and organizations. *Addiction, 110*, 1070–1072.

Kozlowski, L. T., & Edwards, B. Q. (2005). "Not safe" is not enough: Smokers have a right to know more than there is no safe tobacco product. *Tobacco Control, 14*(Suppl. 2), ii3–ii7.

Kozlowski, L. T., Heatherton, T. F., Frecker, R. C., & Nolte, H. E. (1989). Self-selected blocking of vents on low-yield cigarettes. *Pharmacology Biochemistry and Behavior, 33*, 815–819.

Kozlowski, L. T., & O'Connor, R. J. (2003). Apply federal research rules on deception to misleading health information: An example on smokeless tobacco and cigarettes. *Public Health Reports, 118*, 187.

Kozlowski, L. T., O'Connor, R. J., Quinio Edwards, B., & Flaherty, B. P. (2004). Most smokeless tobacco use is not a causal gateway to cigarettes: Response to Tomar & Loree 2004. *Addiction, 99*, 262–264.

Kozlowski, L. T., O'Connor, R., & Edwards, B. Q. (2003). Some practical points on harm reduction: What to tell your lawmaker and what to tell your brother about Swedish snus. *Tobacco Control, 12*, 372–373.

Lee, P. N. (2013). Epidemiological evidence relating snus to health – an updated review based on recent publications. *Harm Reduction Journal, 10*, 36.

Levy, D. T., Mumford, E. A., Cummings, K. M., Gilpin, E. A., Giovino, G., Hyland, A., et al. (2004). The relative risks of a low-nitrosamine smokeless tobacco product compared with smoking cigarettes: Estimates of a panel of experts. *Cancer Epidemiology, Biomarkers and Prevention, 13*, 2035–2042.

Liu, S. T., Nemeth, J. M., Klein, E. G., Ferketich, A. K., Kwan, M. P., & Wewers, M. E. (2015). Risk perceptions of smokeless tobacco among adolescent and adult users and nonusers. *Journal of Health Communication, 20*, 599–606.

Lund, I., & Lund, K. E. (2014). How has the availability of snus influenced cigarette smoking in Norway? *International Journal of Environmental Research and Public Health, 11*, 11705–11717.

Lund, K. E. (2012). Association between willingness to use snus to quit smoking and perception of relative risk between snus and cigarettes. *Nicotine & Tobacco Research, 14*, 1221–1228.

MacCoun, R. (2013). Moral outrage and opposition to harm reduction. *Criminal Law and Philosophy, 7*, 83–98.

Macy, J. T., Li, J., Xun, P., Presson, C. C., & Chassin, L. (2015). Dual trajectories of cigarette smoking and smokeless tobacco use from adolescence to midlife among males in a Midwestern US community sample. *Nicotine & Tobacco Research*.

Mayo Clinic (2015). *Chewing tobacco: Not safer than cigarettes*. Retrieved from http://www.mayoclinic.org/healthy-lifestyle/quit-smoking/in-depth/chewing-tobacco/art-20047428

Maziak, W. (2014). Harm reduction at the crossroads: The case of e-cigarettes. *American Journal of Preventive Medicine, 47*, 505–507.

McCambridge, J. (2015). Accounting for the masters of deception. *Addiction, 110*, 1072–1073.

McKenna, J. W., Pechacek, T. F., & Stroup, D. F. (2003). Health communication ethics and CDC quality-control guidelines for information. *Public Health Reports, 118*, 193–196.

McNeill, A. B. L., Calder, R., Hitchman, S. C., Hajek, P., & McRobbie, H. (2015). *E-cigarettes: An evidence update*. Public Health England.

National Cancer Institute (2001). *Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine. Smoking and Tobacco Control Monograph 13*.

National Cancer Institute (2015). *Smokeless Tobacco and Cancer*. Retrieved from http://www.cancer.gov/about-cancer/causes-prevention/risk/tobacco/smokeless-fact-sheet#q7

Nutt, D. J., Phillips, L. D., Balfour, D., Curran, H. V., Dockrell, M., Foulds, J., et al. (2014). Estimating the harms of nicotine-containing products using the MCDA approach. *European Addiction Research, 20*, 218–225.

O'Connor, R. J., Flaherty, B. P., Quinio Edwards, B., & Kozlowski, L. T. (2003). Regular smokeless tobacco use is not a reliable predictor of smoking onset when psychosocial predictors are included in the model. *Nicotine & Tobacco Research, 5*, 535–543.

Office of Management and Budget (2002). In Office of the President (Ed.), *Guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by Federal agencies; Republication* (Vol. 67, pp. 8452–8460). Washington, DC: Federal Register.

Phillips, C. V. (2015). Gateway effects: Why the cited evidence does not support their existence for low-risk tobacco products (and what evidence would). *International Journal of Environmental Research and Public Health, 12*, 5439–5464.

Piano, M. R., Benowitz, N. L., Fitzgerald, G. A., Corbridge, S., Heath, J., Hahn, E., et al. (2010). Impact of smokeless tobacco products on cardiovascular disease: Implications for policy, prevention, and treatment: A policy statement from the American Heart Association. *Circulation, 122*, 1520–1544.

ProCon.org (2014). *35 FDA-approved prescription drugs later pulled from the market*. Retrieved from http://prescriptiondrugs.procon.org/view.resource.php?resourceID=005528

Proctor, R. N. (2013). Why ban the sale of cigarettes? The case for abolition. *Tobacco Control, 22*, 27–30.

Royal College of Physicians (2007). *Harm reduction in nicotine addiction: Helping people who can't quit*. London: Royal College of Physicians.

Saddleson, M. L., Kozlowski, L. T., Giovino, G. A., Goniewicz, M. L., Mahoney, M. C., Homish, G. G., et al. (2016). Enjoyment and other reasons for electronic cigarette use: Results from college students in New York. *Addictive Behaviors, 54*, 33–39.

Savitz, D. A., Meyer, R. E., Tanzer, J. M., Mirvish, S. S., & Lewin, F. (2006). Public health implications of smokeless tobacco use as a harm reduction strategy. *American Journal of Public Health, 96*, 1934–1939.

Scientific Committee on Emerging and Newly Identified Health Risks (2008). *Scientific opinion on the Health Effects of Smokeless Tobacco Products*. Retrieved from http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_013.pdf

Strasser, A. A., Orom, H., Tang, K. Z., Dumont, R. L., Cappella, J. N., & Kozlowski, L. T. (2011). Graphic-enhanced information improves perceived risks of cigar smoking. *Addictive Behaviors, 36*, 865–869.

Stratton, K. R. (2001). *Clearing the smoke: Assessing the science base for tobacco harm reduction*. Washington, DC: Institute of Medicine, National Academy Press.

Substance Abuse and Mental Health Services Administration (2015). *Tips for teens: Tobacco Info*. Retrieved from https://store.samhsa.gov/shin/content/PHD633/PHD633.pdf

Tam, J., Day, H. R., Rostron, B. L., & Apelberg, B. J. (2015). A systematic review of transitions between cigarette and smokeless tobacco product use in the United States. *BMC Public Health, 15*, 258.

Tomar, S. L., Alpert, H. R., & Connolly, G. N. (2010). Patterns of dual use of cigarettes and smokeless tobacco among US males: Findings from national surveys. *Tobacco Control, 19*, 104–109.

Tomar, S. L., Fox, B. J., & Severson, H. H. (2009). Is smokeless tobacco use an appropriate public health strategy for reducing societal harm from cigarette smoking? *International Journal of Environmental Research and Public Health, 6*, 10–24.

U.S. Department of Health and Human Services (2010). *O.D.P.H.P. National Action Plan to Improve Health Literacy*. From http://health.gov/communication/hlactionplan/pdf/Health_Literacy_Action_Plan.pdf

United States Code (2009). Family smoking prevention and tobacco control act United States. In *Stat 1776*.

United States Public Health Service. Office of the Surgeon General (2014). *The health consequences of smoking – 50 years of progress: A report of the Surgeon General*. Rockville, MD. US Department of Health and Human Services, Public Health Service, Office of the Surgeon General.

Vanyukov, M. M., & Ridenour, T. A. (2012). Common liability to drug addictions: Theory, research, practice. *Drug and Alcohol Dependence, 123*(Suppl. 1), S1–S2.

Warner, K. E., Ernster, V. L., Holbrook, J. H., Lewit, E. M., Pertschuk, M., Steinfeld, J. L., et al. (1986). Promotion of tobacco products: Issues and policy options. *Journal of Health Politics, Policy and Law, 11*, 367–392.

Watson, M. C., & Forshaw, M. (2015). Why we shouldn't normalise the use of e-cigarettes. *BMJ, 351*, h3770.

Wilson, D. (2009). A vote nears for a tobacco bill that Philip Morris can live with. *The New York Times* New York.

Zeller, M. (2012). *The FDA Center for Tobacco Products: 20 Years layer: Returning to FDA to Regulate Tobacco*. Retrieved from http://www.fda.gov/downloads/AboutFDA/Transparency/Basics/UCM378104.pdf