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Commentary

Young or adult users of multiple tobacco/nicotine products urgently need to be informed of meaningful differences in product risks

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ABSTRACT

Previously, it has been argued that health information efforts need to inform the public about meaningful differential risks from tobacco/nicotine products. The fact of multiple product use by the same individual further supports this need. When the majority of youth, for example, who use smokeless tobacco are also current tobacco smokers, it makes little sense to mount a smokeless prevention campaign that fails to include clear messages about the much greater risks from smoking. In April 2016, The Food & Drug Administration (FDA) announced a \$36 million campaign for youth that “smokeless doesn't mean harmless.” Research shows the public (a) already knows that smokeless tobacco is not harmless, but are (b) also largely unaware that cigarettes are much more harmful than smokeless. Though not harmless, smokeless tobacco has been estimated to be over 90% less harmful than cigarettes. ‘Gateway’ fears are made moot by current use of multiple tobacco/nicotine products. When multi-tobacco product use is commonplace among users, usable information on significant differences in risk is crucial for both adult and younger users. The FDA and like campaigns and health information websites should follow established ethical principles and accepted communication methods to inform the public of less-harmful tobacco/nicotine products as well as the greater harms of smoking, in keeping with the Surgeon-General's advice that reductions in smoking in particular will bring about the greatest public health advances.

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1. Considering youth who are already smoking and using other tobacco/nicotine products

Much of the public education effort on the use of tobacco/nicotine products is directed at preventing never users of any tobacco/nicotine products from becoming ever users of any tobacco/nicotine product (National Center for Chronic Disease Prevention and Health Promotion, 2014). The fear of the ‘gateway’ effect is fueled both by the desire to prevent any tobacco/nicotine use as well as the desire to prevent subsequent cigarette smoking. As laudatory as these efforts are, they neglect the impact on adult consumers as well as the predicament experienced by many high-risk youth who have already crossed through (thus rendering moot) any arguable ‘gateway’ because they are already current users of tobacco cigarettes as well as a range of other tobacco/nicotine products. These consumers and potential consumers have a fundamental right (based on the principles of autonomy,

health communication, and health literacy) to be well aware of the dramatic differential harms from the various products they are already or might consider using (Kozlowski & Sweanor, 2016).

This ‘debate’ argues that we need to recognize the critical issue of multiple tobacco/nicotine product use for high-risk youth as well as tens of millions of American adults, and to be educating these consumers, whether youth or adults, about major differential harms from different products they are already using. For those who might oppose informing everyone of the major differential harms of tobacco/nicotine products, they should recognize the even more persuasive arguments for providing such information to the many (young or old) that are already using multiple tobacco/nicotine products. Even if ethically defensible (which we do not believe to be the case) it should also be appreciated that there would be no practical way to limit the availability of accurate health information so that it would only reach adults or only high-risk youth. These issues will be discussed herein.

Our examples focus on smokeless tobacco (ST) and cigarette use because (1) the differential harms are very well-established and very large (discussed below), (2) the level of dual use is high for youth (e.g., 60% of high school males who used ST in the past 30 days also smoked (Tomar, Alpert, & Connolly, 2010)), and (3) the U.S. Food and Drug Administration (FDA) has recently announced a \$36 million youth-targeted

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campaign on the harms from ST (U.S. National Library of Medicine, 2016) that fails to directly warn about the much greater harms from smoked tobacco (predominantly cigarettes). Although the FDA is framed as a ‘prevention’ campaign, surely such a campaign would hope to prevent the development of regular daily use of ST by those who have only experimented with use.

2. Preventing youth use of tobacco/nicotine

Protecting children has long had a special place in the rhetoric and practice of tobacco/nicotine policy. For a young person, before the age of majority, to become addicted to a tobacco/nicotine product is an event that everyone can agree is more troubling than for an adult for whom one can generally assume much greater responsibility for ill-advised actions. While there has been an understandable ‘zero-tolerance’ for youth using tobacco/nicotine, it is clear that youth has been and will likely continue to be the period in which the large majority of users start (National Center for Chronic Disease Prevention and Health Promotion, 2014). ‘Zero-tolerance’ for use by youth should be sought, but there is an abiding reality that nicotine-use prevention efforts are imperfectly effective, just as abstinence campaigns are for other risky substance-use behaviors engaged in by youth (Johnston, O’Malley, Schulenberg & Miech, 2014). Prevention efforts can help keep product usage by youth to lower levels, but they have never completely prevented experimentation or regular use. The young person who is already using some tobacco products should be recognized as being at especially high risk of using other tobacco/nicotine products and developing more frequent use patterns.

3. Use of both smokeless and smoke is very common among young smokeless users

In 2012, more youth (aged 12–17) both smoked (any smoked product) and used smokeless (57%) than used smokeless only (43%) (Table 13.14) (National Center for Chronic Disease Prevention and Health Promotion, 2014). In 2014, 44% of 12th grade males who used smokeless also smoked cigarettes (Johnston, Miech, O’Malley, Bachman & Schulenberg, 2014). A targeted anti-ST campaign should make use of this important opportunity for educating such dual/multi tobacco product users about comparative risk information of direct relevance to them. Looking at the transition patterns for ST and smoking across a few studies in adolescents and adults, it was clear that dual use at time 1 was linked to significant percentages of continued use 4 years later: for adult males, 44.3% were dual users, 27% were exclusive smokers, 17.4% were exclusive ST users; for adolescents, 20.4% were dual users, 31.3% were exclusive smokers, 34.2% were exclusive ST users (Tam, Day, Rostron, & Apelberg, 2015). These patterns argue for educating these consumers about major differential product risks.

The special problem of multiple product use has been acknowledged by FDA and National Cancer Institute researchers (Kaufman, Land, Parascandola, Augustson, & Backinger, 2015): “Findings suggest that adolescents who use multiple tobacco products are likely to continue such use as they move into young adulthood. When addressing tobacco use among adolescents and young adults, multiple forms of tobacco use should be considered.” (p.251). Others have encouraged based on their research that “Public health interventions and communication campaign messages focused on tobacco prevention and control may be useful in decreasing concurrent tobacco product use, especially if they target beliefs and/or poly-tobacco use of products as opposed to single tobacco product use only” (Kowitz et al., 2015).

4. Alleged causal ‘gateways’ are limited issues to begin with, but become largely irrelevant for those who already use multiple products

Although concerns about causal drug gateways have considerable political power and rhetorical force (Bell & Keane, 2014), their scientific

substance is very limited (Degenhardt et al., 2010; Kleinig, 2015; Kozlowski, 2015b; Kozlowski & Abrams, 2016; Rodu & Cole, 2010; Vanyukov et al., 2012). Longitudinal observational studies cannot establish that (a) prior use of product A causes the use of product B (Phillips, 2015) and (b) that other associated influences on product use (e.g., characteristics of the individual user, risk-taking or use of still other drug products) have not been responsible or strong contributors to movement to other products (Vanyukov & Ridenour, 2012). In the case of snus (Swedish ST) use in Scandinavia, concern for a causal gateway to cigarettes has not been supported by the research ((Lund & Lund, 2014; Scientific Committee on Emerging and Newly Identified Health Risks, 2008).

Causal gateway concerns should be moderated by the actual likelihood of progression from the lower-risk product to the higher risk, which in turn can be shaped by marketing effects and public policy (Kozlowski, 2007; Kozlowski, 2015a). If a minority of initial users of the lower-risk product move on to regular use of the more dangerous product, this is not an indication of a gateway that will be important for population health unless it results in a greater overall number of smokers (Kozlowski & Abrams, 2016; Levy et al., 2017). Also, if a majority of users of the less-harmful product do not move on to regular use of the more dangerous product, then this would be consistent with some users possibly being prevented from using the more dangerous product because of the use of the less-harmful product.

But the gateway issue is moot for the many young ST users who are already smoking. Once the individual already smokes and uses smokeless or other tobacco/nicotine products, to worry about gateways is like worrying about shutting the barn door after the horse has escaped. The priority for this group of multiple-tobacco/nicotine product users should be to try to reduce risks as much as possible, *if cessation of all tobacco/nicotine products cannot be achieved.*

Concerns about possible net negative effects of population health of lower-risk products have been a fundamental issue (Kozlowski, Strasser, Giovino, Erickson, & Terza, 2001; Stratton, 2001). This issue has been discussed in detail (Kozlowski & Sweanor, 2016) and suppression of accurate health information should not be justified by ‘concerns,’ but rather would need actual, persuasive evidence of net ill-effects—which is non-existent (Kozlowski & Sweanor, 2016).

But what about adverse effects on brain development? The weakness of gateway arguments and evidence has contributed to the focus on another concern about the effects of nicotine on the developing brain (Kozlowski & Abrams, 2016). For example, Chris Hansen, President of the American Cancer Society Action Network said: “There is no reason for a teen to use any tobacco product. Nicotine exposure at a young age can cause lasting harm to brain development, and the addiction to nicotine often lasts for life.” (American Cancer Society Action Network, 2015). This over-arching goal of protecting youth from these products should be tempered by recognition that once tobacco use has started, no matter the age of the user, harm reduction and so-called tertiary prevention are important.

5. But aren't kids, even adolescents, special cases?

While there are concerns about the ability of adolescents to assess and act upon risk information and adults may be somewhat better at it, adolescents are often judged to have the capacity to give informed consent on important matters and do respond to well-presented risk information in a way that is similar to adults (Millstein & Halpern-Felsher, 2002; Reyna & Farley, 2006; Rivers, Reyna, & Mills, 2008; Scott & Wollard, 2013; Steinberg, 2008; Steinberg & Cauffman, 1996). One expert concluded: “In sum, adolescents’ greater involvement than adults in risk-taking does not stem from ignorance, irrationality, delusions of invulnerability, or faulty calculations” (Steinberg, 2008). Close analysis of the ability of adolescence and adults to perceive and assess risks shows more similarity than differences (Beyth-Marom, Austin, Fischhoff, Palmgren, & Jacobs-Quadrel, 1993). Tobacco control might

also attend to progress in sex education in the schools, where it has been recognized that “abstinence only” and “harm reduction” educational programs can in fact be combined, and some of these “comprehensive” programs have shown positive effects on both sexual abstinence and condom usage by the non-abstinent (Weed, 2012).

6. FDA's smokeless tobacco 'doesn't mean harmless' campaign in the United States tells people what they already know

The FDA's new \$36 million campaign is targeted at rural youth on the dangers of ST, to discourage use of smokeless. This component of their broader “Real Costs” campaign features the message “smokeless doesn't mean harmless” (U.S. National Library of Medicine, 2016). The campaign helps to spread information available in FDA warning labels that have been required since 2010 and have given evidence of effectiveness (Agaku, Singh, Rolle, & Ayo-Yusuf, 2016). Warnings on smokeless products and in advertisements inform that ST products “are not a safe alternative to cigarettes,” “can cause mouth cancer,” “can cause gum disease and tooth loss,” and “are addictive.” It appears that very few people, fewer than 1 in 100, actually do think smokeless is harmless. For example, a 2015 study of 116 residents in Appalachian Ohio (an example of a targeted region for the campaign) included 53 adolescents, 63 adults, both ST users and nonusers, and found that *all* adolescents and *all-but-one* adult (i.e., 99% overall) “identified both short- and long-term health consequences of ST use,” most commonly noting immediate health problems linked to the mouth (Liu et al., 2015).

7. While the public already knows that smokeless doesn't mean harmless, it is ignorant that smoking means much more danger than smokeless

Remarkably, nowhere in the FDA smokeless campaign is it made clear that cigarette smoking is much more dangerous to health than is ST. A recent, representative survey conducted by the National Cancer Institute, asked “In your opinion, do you think that some smokeless tobacco products, such as chewing tobacco, snus and snuff are less harmful to a person's health than cigarettes?” with answer options of Yes, No, Don't know. Most respondents (74%) answered “No,” with 17% reporting they “did not know,” and only 9% reporting, “Yes” (Kiviniemi & Kozlowski, 2015). A recent national survey of youth in the U.S. found that 58.2% reported that ST had “about the same” risk as cigarettes and 31.8% reported that it was “more risky” than cigarettes and only 7.1% reported that ST was “less risky” than cigarettes (2.8% said “Don't Know”) (Wackowski & Delnevo, 2016). It is remarkable that about 4 1/2 times as many respondents said ST was “more risky” than cigarettes than less said it was “less risky” than cigarettes; and the large majority (about 93%) did not appear to know that ST was less risky than cigarettes!

8. Manufactured smokeless tobacco in the United States is fundamentally less harmful than smoking

ST here refers to manufactured smokeless as available in the United States and Sweden. The products used in India, for example, have been found to be much more dangerous than these ST products to health (O'Connor, 2012). The differences in absolute risks are meaningful and easily expressed. ST does not cause lung cancer and the deadly respiratory diseases (e.g., chronic obstructive lung disease) responsible for the majority of cigarette deaths (National Center for Chronic Disease Prevention and Health Promotion, 2014; Scientific Committee on Emerging and Newly Identified Health Risks, 2008). Include the much lower cardiovascular disease risks from ST (Piano et al., 2010) and, arguably, no serious tobacco-disease risks for U.S. smokeless products are greater than for cigarettes (not even oral cancer) (Dampousse, Mowls, & Beebe, 2015; Gao, Prasad, & Zacharias, 2014; Weitkunat, Sanders, & Lee, 2007). Clearly this “not harmless” product is *importantly*

greatly less harmful than cigarettes (Colilla, 2010; National Center for Chronic Disease Prevention and Health Promotion, 2014; Nutt et al., 2014; Scientific Committee on Emerging and Newly Identified Health Risks, 2008; Stratton, 2001). A recent summary estimates that manufactured ST as found in the United States would be at least 90% less harmful than cigarettes (Nutt et al., 2014).

9. Official avoidance of providing health information on differential risks from tobacco/nicotine products

FDA's failure to provide comparative risk information is consistent with a major trend. For decades in the United States, health authorities have failed to provide accurate differential risk information on tobacco products (Kozlowski & O'Connor, 2003; Kozlowski & Sweanor, 2016). For example, the U.S. Surgeon-General's online ‘Report for Kids’ featured the question, “Is smokeless tobacco safer than cigarettes?” and provided the headline answer, “No Way!” while going on to itemize a list of risks that was much shorter and less deadly than the known lists for cigarettes (Kozlowski & O'Connor, 2003). Until April 2016, the Mayo Clinic website indicated that ST was as dangerous as cigarette smoking (Kozlowski & Sweanor, 2016). In much publicized testimony before a Congressional committee in 2003, the then Surgeon-General Richard Carmona said, “No matter what you may hear today or read in the press reports later, I cannot conclude that the use of any tobacco product is a safer alternative to smoking” (Myers, 2003). Yes, he said it wasn't “safer,” a scientifically unsupported position even then, thus giving his official imprimatur as the nation's MD on health information for a campaign that misleads the public.

10. Existing trends and patterns in tobacco product use are so corrupted by disinformation or error that they provide little indication of what might happen if accurate information were widely understood by the public

While there is an emerging literature on dual use and trajectories of product use among dual and poly-tobacco product users (Macy, Li, Xun, Presson, & Chassin, 2016; Mejia & Ling, 2010; Messer et al., 2015; Tam et al., 2015), these results need to be assessed in the context of (a) extensive promotion by agencies that ST is as dangerous or more dangerous than smoking ((Kozlowski & O'Connor, 2003; Kozlowski & Sweanor, 2016) (b) and the public themselves having very inaccurate ideas of the comparative risks of ST and cigarettes (Kiviniemi & Kozlowski, 2015). What conclusions would one draw about the purchase of safer cars if it were the case that the public had mainly inaccurate information available or promoted to them about which cars were safer? (and surely a campaign to inform the public that “Volvos don't mean harmless” would be open to ridicule). The current patterns of use of smokeless and cigarettes tell us little about what consumers would do if (a) they appreciated the risk differential and (b) marketing supported their use of lower-risk products (Kozlowski, 2007) by such means as differential taxation (Chaloupka, Sweanor, & Warner, 2015).

Evidence from Norway supports that consumer perception of lower risks from snus vs. cigarettes has been important in promoting smoking cessation using snus (Lund, 2012). Behavioral economics research on ST and cigarettes also indicates that providing differential risk information can promote harm reduction (Rousu et al., 2014). Without educating smokeless/smoke users that smoking is much worse than smokeless, how many of these smokers might take only the step of giving up ST? The campaign offers no clear and direct messages that smoking is much more deadly than smokeless, despite the reality of current massive misinformation and consumer ignorance, and focuses its multi-million dollar educational effort on telling the public what is already well-known—“smokeless doesn't mean harmless.” Although an inference of greater risk from cigarettes might be drawn from separate elements of the Real Cost campaign against smoking, direct comparisons are warranted, especially for dual users of combusted and non-combusted

products and in light of the state of overall consumer misinformation on the topic.

11. Major differential risks should guide policies and practice

Authorities have encouraged that tobacco policy be informed by significant differential risks (e.g., Zeller, 2013). The 2014 Surgeon-General Report has forcefully made the same point that smoking carries by far the greatest risk of death and disability from tobacco (National Center for Chronic Disease Prevention and Health Promotion, 2014). Yet, the FDA is missing an opportunity with the current smokeless campaign to provide accurate information on major differences in risks of products that high-risk youth and many adults are using. Some millions of the Real Cost campaign should be directed to the many, higher-risk, young, often experimenting, smokeless users who also smoke, to discourage movement from smokeless to smoke and to also encourage smoking cessation. Or to the millions of smokers who do not now use smokeless but who might consider a switch from smoking, or to those consumers switching from smokeless to smoking due to economic considerations.

12. Communicating risk and differential risk

Risk communication has been the object of considerable research, and there are challenges to do it in ways that contribute to health literacy (U.S. Department of Health and Human Services, O. o. D. P. a. H. P, 2010) and public health ethics (Gostin, 2008; Kozlowski & Sweanor, 2016; Office of Management and Budget, 2002). On other topics, the FDA has employed good evidence-based recommendations for communicating risks and acknowledges that health communication by FDA needs to inform consumers of products and actions differing in risk. FDA's Strategic Plan for Risk Communication identifies three key principles (Fischhoff, Brewer, & Downs, 2001). First, that communication should be based on science. The science on the major difference in absolute risks from ST versus cigarettes is clear-cut and has been so for decades. There is also an extensive science base on how to communicate risk differential by means of graphics and representations of differences in absolute risk (Fischhoff et al., 2001). The second principle is;

Communication should inform choices. Unless people know the risks and benefits of possible actions, they cannot evaluate the choices facing them. As a result, communications must focus on conveying the risks and benefits of those choices. That is true whether the organization hopes people will make a particular choice (e.g., get vaccinated) or is indifferent (e.g., use a drug that has been approved for sale). (p.225)

The third principle is that “communications should be results oriented.” These principles are also consistent with the federal government's commitment to provide information to the public that is high quality, objective, useful, and has integrity (Office of Management and Budget, 2002). Communicating risks, including differences in risk, in an accurate, understandable, useable way has been accepted as a standard element of health practice (Naik, Ahmed, & Edwards, 2012). More research can help develop more effective ways to inform the public (e.g., Strasser et al., 2011).

Users of multiple products should know of accurate, actionable differential product risks—no matter their age. The information for current multiple users of course cannot be provided only to them or only to adults, and never users and users of only one product may be influenced by this information too. Fears of the *possibility* of negative consequences for some cannot justify suppressing or omitting health relevant information—especially when there is no actual evidence that there would be any net negative effects on population health (Kozlowski & Sweanor, 2016). Such a quarantine of accurate public health information that violates the fundamental and accepted principles of informed

consent, personal autonomy, and fair consumer practices would need to be based on persuasive evidence that net losses to public health would occur (Kozlowski & Sweanor, 2016).

13. Electronic cigarettes and vaping

We have focused on ST, but we think arguments can also now be made based on significant evidence that electronic cigarettes (vape) are virtually certain to be significantly safer than cigarettes, even though like any consumer products also are “not harmless.” Credible current estimates are that they are likely to be at least 95% less harmful than cigarettes (McNeill et al., 2015; Royal College of Physicians, 2016).

14. Key recommendations

- The public and especially users of multiple tobacco/nicotine products need to be provided accurate and actionable information on major differential tobacco/nicotine product risk.
- This recommendation applies equally to youth who are using prohibited products and adults who are using legal products.
- Deception or evasion about major differences in product risks is not supported by public health ethics, health communication or consumer practices.
- Public health agencies have an obligation to correct the current dramatic level of consumer misinformation on relative risks that they have fostered.

Ethical and effective public health campaigns need to respect and work with consumers to facilitate better informed choices. Campaigns that fail to address existing misinformation that may be leading to much more hazardous behaviors, and worse, campaigns that continue deceptions, can be expected to impose a ‘real cost.’ Cigarettes companies have been ordered by the courts to correct the misleading information about their products that they provided to the public (Tobacco Companies Are Told to Correct Lies About Smoking, 2012) that in effect mislead the public about the risks of lower-tar cigarettes. Similarly, health groups and agencies who continue to keep the public misled or ill-informed about the significant harm reduction from ST in contrast to cigarettes should be actively working to correct the incorrect understanding of the differential risks that they have so long fostered directly or indirectly (Kozlowski & Sweanor, 2016).

We need to see beyond the value of fundamentally uninformative or misleading messages that mainly say “not safe” or “not harmless”, and work to promote better understanding by consumers of the products that are being used by youth and adults. Such public health education should not be left in the hands of an industry marketing products to simply promote sales (e.g., Dave & Saffer, 2013). Health-focused agencies need to regain some credibility in communicating about tobacco/nicotine product risks and work to place it responsibly in the context of comprehensive public health activities.

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