Misleading the public for their own good? Changing the warnings on snus

written by Clive Bates | 27 November 2014

Misleading labels implicitly exaggerating risk? These are the current U.S. snus warnings

What sort of 'warnings' should go on tins of snus? Modern snus use is probably around 98% less risky than smoking – but do the regulatory 'risk communications' in the form of these warnings really reflect that? Do they give the consumer useful information that helps them make decisions about which risks they are willing to bear and the options they have to reduce risks associated with tobacco or nicotine use? It's an interesting time for these questions: the United States is in the middle of a process that might lead changes to these warnings on some snus packaging.

The U.S. tobacco products regulator, the FDA, has a process by which makers of tobacco products with reduced risk can apply to be allowed to make claims of reduced risk in communications to the public. This is called the Modified Risk Tobacco Product (MRTP) application. Basically, a tobacco company (and in future maybe e-cigarette companies) have to submit evidence to justify a claim that their product is less risky than something it is compared to, for example cigarettes. The snus manufacturer Swedish Match has submitted the first MRTP application for the products it has on sale in the United States. This is currently out for

consultation and you can respond here (closing date 23 February 2015). The application is vast, apparently running to 130,000 pages. It has an 850 page summary narrative… but I have extracted a mere 45-page summary. In short, Swedish match is requesting changes to the warnings used on snus packaging in the U.S:

> *WARNING: This product can cause mouth cancer. This would be dropped.*
> *WARNING: This product can cause gum disease and tooth loss. This would be dropped.*
> *WARNING: This product is not a safe alternative to cigarettes. This would be replaced with: "WARNING: No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes"*
> *WARNING: Smokeless tobacco is addictive. This would be retained.*

In other words, they propose modest sensible and evidence-based changes to warnings. The third of these changes is really quite important (if obvious) for real public health advocates as it establishes a 'proof of concept' for harm reduction endorsed by a leading regulator, and emphasises the importance of communicating risk fairly. However, there are some tobacco control activists who do not want this to happen. Let us consider three submissions:

1. A submission by a group of experts outlining the reasons for accepting the changes.

2. A submission by Counterfactual (me) discussing ethical and framing issues.

3. A submission by Dr Lucy Popova and Professor Stanton Glantz in favour of keeping the warnings as they are.

In this positing I provide access to the three submissions and comment on the intent and ethics of the third, and explain why the case made actually supports the changes to the warnings that Professor Glantz opposes.

1. Submission by nicotine science and

policy experts – the case for allowing the proposed changes

Docket: FDA-2014-N-1051 –

Submission in PDF format: Submission to FDA on the MRTP application of Swedish Match

18 November 2014

Professor Tony Axéll
Mr Clive Bates
Professor Ron Borland
Professor John Britton
Professor Jean François Etter
Dr Konstantinos Farsalinos
Professor Peter Hajek
Professor Martin Jarvis
Professor Lynn Kozlowski
Dr Michael Kunze
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Dr Karl Erik Lund
Professor Ann McNeill
Professor Riccardo Polosa
Dr Lars Ramström
Professor Gerry Stimson
Professor David Sweanor

Please accept this contribution to the FDA consultation on the Modified Risk Tobacco Product application made by Swedish Match for its snus products. [Swedish Match North America MRTP Applications]. In our view, the available scientific literature supports the regulatory conclusions drawn in the application.

We write as experts in the field of nicotine science and public health policy. We wish to make the following observations relevant to FDA's examination of this application:

1. *Disease risk associated with use of modern Swedish-style snus is very low or negligible relative to that generated by use of cigarettes and is*

not exceptional compared to other risks routinely accepted in society. The evidence base provides unequivocal support for the contention that snus is a reduced risk product within the definition a Modified Risk Tobacco Product.

2. *The experience of Sweden and Norway suggests significant and continuing population public health benefits have been achieved as a result of use of snus as an alternative to smoking or use of snus to quit smoking. In the country (Sweden) where snus use has been widespread and increasing among men, it is now clear that mortality attributable to tobacco among men is lower than in any other EU Member State and that the use of snus has been an important contributor to this situation It is no longer appropriate to discuss the risks of snus use without reflecting the benefits of switching from smoking to snus or using snus instead of ever starting smoking, and this applies equally to the growing market for snus in the United States.*

3. *Misleading warnings may cause actual harm to health and contribute to unnecessary disease and death. If smokers are convinced that snus is more risky than it is, it is possible that some will be deterred from switching, or will be more indifferent to the choices they make between different tobacco products. If there is an undeclared aim to use warnings, known to be misleading, to deter smokeless tobacco use rather than to provide accurate risk information, this would be unethical and inappropriate regulation.*

4. *The current generic warning: "WARNING: This product is not a safe alternative to smoking" is too ambiguous to be useful in helping users make decisions about tobacco use. It could refer to any level of risk between 'almost as dangerous as smoking' and 'almost as safe as not smoking'. It is unlikely that consumers will guess correctly the appropriate realistic point in this range, and the warning is in effect meaningless and likely to be misleading for most people seeing it.*

5. *As the FDA recognises a continuum of risk in the products that deliver recreational nicotine, it is important not to deny this insight in warnings the public. It is appropriate therefore to replace the generic warning: "WARNING: This product is not a safe alternative to smoking" with the*

more subtle, complete and informative message "WARNING: No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes". Equally, it would be inappropriate not to do this, given the relative risks of snus use and smoking.

6. *The risks of unintended consequences arising from the revised generic warning are slight: it is impossible to interpret this as implying no risk, and 'substantially lower' could easily still imply far greater risk than there actually is. The new warning is unlikely to mislead dual users, who will still see warnings of high risks on the cigarettes they consume. It would be unreasonable to deny the users of snus accurate warnings because of hypothetical and unlikely confusion of risks in dual users.*

7. *It is implicitly misleading to warn of specific risks that are negligible, especially if the undeclared purpose of this is to manipulate behaviour by creating a sense of revulsion rather than accurately communicate risk. The specific warnings: "WARNING: This product can cause mouth cancer"and "WARNING: This product can cause gum disease and tooth loss" are no longer justified.*

8. *It is premature to remove health warnings entirely and it remains justified to retain a warning about the addictiveness of snus: WARNING: Smokeless tobacco is addictive as there is no dispute that nicotine delivered through snus may form dependence.*

9. *FDA should address the anomaly that will arise if the new warnings can be used on the applicant's products, but cannot be generalised to physically and functionally similar products, such as other products complying with the Gothiatek standard. In that situation, continued use of the existing warnings may be overtly misleading and not serving public health. However, we recognise that the MRTP process requires a tobacco company to have the incentives to make an application in the first place, and those incentives may include exclusive use of the reduced risk claim. We invite FDA to consider if the process for applying and approving MRTP applications creates the right incentives to maximise the public health benefit of reduced risk products.*

10. *The MRTP regime is flexible enough to take account of new evidence*

and to adjust warnings if necessary. This implicitly, and correctly, recognises an element of uncertainty but acknowledges that regulators have to make determinations based on the available evidence and their judgement, taking account of the reality that the case for retaining the status quo does not have a convincing evidence base.

We hope FDA Center for Tobacco Products and the Tobacco Products Scientific Advisory Committee will take these views into account.

Yours faithfully,

[signatures / affiliations]

2. Submission by Counterfactual – ethical and framing issues

I signed the one above, but the next one by me alone. It focuses more on conceptual and framing questions, such as precautionary principle, rights and responsibilities, and how the FDA should consider these issues. Note how bizarre this system is: for American consumers to be given realistic information about tobacco product risks relies on tobacco companies deciding it is in their commercial interest to make these applications. If it doesn't look profitable, then the warnings default to false and misleading warnings mandated by the FDA. So this focusses on the the way these decisions should be made. Full submission (5 pages) is here: Framing issues in evaluating a Modified Risk Tobacco Product application – here are the headings and conclusions.

Comments on the MRTP application of Swedish Match *[Docket: FDA-2014-N-1051]*

Headings

- *A 'materiality' test should apply to warning messages or warnings will be debased*
- *Beyond merely true: the importance of proportionality and realistic comprehension*

- *The precautionary principle cannot apply*
- *Warning messages should inform consumers not manipulate their behaviour*
- *Use of miscommunication of risk to purposefully modify behaviour is unethical*
- *Regulatory hurdles to truthful communication will harm health*
- *Regulators have the responsibility (and liability) for realistic risk communication*
- *Generic versus specific applications – distortions of competition*

Conclusions

1. *The warnings related to specific disease risks fail a reasonable materiality test and should be removed. There is no case for retaining them on a precautionary basis.*

2. *The generic wording proposed by the applicant is far more realistic and proportionate than the existing warnings and should be adopted, but it still implicitly understates the relative risk reduction of snus use compared to smoking. This proposed warning should not be diluted with inappropriately risk-averse hedging language.*

3. *Warnings are to inform consumers' own decisions about risk with accurate information fairly and proportionately communicated. It is unethical purposefully to use miscommunication of risk to try to cause a desired behavioural outcome, such as deterring people from using snus by implicitly overstating its risks.*

4. *FDA should regard the provision of realistic risk communication, as at least in part, as its own responsibility and become proactive in ensuring the warnings it imposes do not mislead consumers. The provision of accurate risk communication to the American public should not be governed by primarily by the commercial calculations of tobacco companies.*

5. *As the continuum of risk in nicotine products evolves, the ability to communicate truthfully and realistically about relative risk will become more important to consumers. It is essential therefore that bureaucratic or regulatory hurdles are kept in proportion and not*

imposed in a way that is harmful to public health. A light touch process is essential for non-combustible products.

6. *FDA should find means to allow the value of scientific analysis provided by an applicant to apply more generically where appropriate and not just to the applicant's own products – but without degrading the incentives to make applications in the first place.*

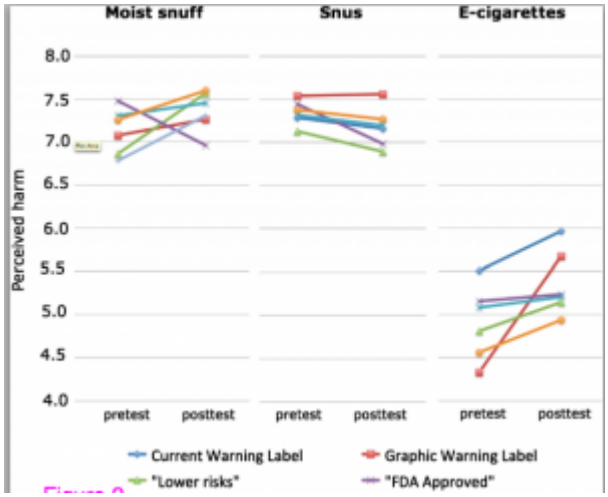
3. Submission by UCSF academics – the case for harming Americans by deliberately misleading them

The case for public bodies to wilfully mislead the public, to protect cigarette sales by making much safer alternatives appear more dangerous than they are, and to create more disease and death through encouraging people into making poor decisions has been made by the tobacco controllers at UCSF, Dr Lucy Popova and Professor Stanton Glantz. Read their submission here: Swedish Match's Consumer Perception Study Provides No Evidence for the Population-Level Effects of Modified Snus Labels.

The gist of the argument made in the UCSF submission is that it is better that people have an unrealistic and excessive perception of risk than an accurate perception, because they hope that this will deter more people out of using the products – exactly the position I ague is unethical in the submission above. They appear unconcerned by the actual risk and accuracy of risk perception In fact, designing communications to create more realistics perceptions is the only defensible approach whatever the outcome, but in this case the outcome is likely to be highly beneficial to health.

To make this argument, UCSF relies on the infamous and highly unethical Popova & Ling study, which has previously been filleted on this blog and destroyed in great depth by Carl Phillips in a letter to the BMC Public Health journal. However, this study actually did create some useful data, but the paper conceals it from the reader. It does not reveal the perception of harm *for smoking*

cigarettes, even though the authors tested that and then declined to include it (a reviewer disclosed this). The paper only shows the perceived harm for snus, moist snuff and e-cigarettes. The Popova & Ling study assessed perception of harm on a 9-point scale, and snus came out in the range 7-7.5. This rather suggests that people in this study grossly over-estimated the risk of using snus relative to smoking, given smoking could only be a bit higher than 7.5 if there is a 9-point scale, and it should be less than 1 if actual risk (approximately 98% lower than smoking) was reflected in perceptions. Here is the chart where Popova and Ling disclose the perceptions of harm.



So the UCSF submission demands that the American public remains mislead and with a grossly exaggerated perception of harm. I hope FDA will request the concealed smoking risk perception data from Popova & Ling and draw the obvious conclusion from it: that risk communication needs to change to more accurately align perceptions of relative risk with reality. UCSF summarises the findings from Popova & Ling:

> *In brief, we found that the proposed warning label ("WARNING: No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes"):*
>
> 1. *significantly lowered perceptions of harm of snus among exclusive smokers*
> 2. *significantly increased positive attitudes towards moist snuff among dual snuff/cigarette users*
> 3. *significantly lowered perceptions of harm of moist snuff among non-users of tobacco*

Good… That is exactly as it should be! The case is made. This could be the one thing the Popova & Ling study is useful for, assuming it isn't taken down for its ethical violations.

Rather than rely on initiative by the FDA's staff, I have asked Popova to release the data, any ethical researcher would agree to this.

> *26 November 2014*
> *Dear Dr Popova*
> *I have read the published paper on your study of risk perceptions, co-authored with Dr Ling, Nonsmokers' responses to new warning labels on smokeless tobacco and electronic cigarettes: an experimental study* *BMC Public Health (2014), **14**:997 doi:10.1186/1471-2458-14-997*. *One of the reviewers pointed out that you had collected data on the perception of harm arising from smoking, though you did not include this in the published paper. It should not have been omitted as it provides an valuable calibration of relative risk of three products (moist snuff, snus, and e-cigarettes) that were the subject of the study in comparison to the dominant product on the market, cigarettes.*
> *I am writing to ask you to release the data on perception of smoking harmfulness that was removed in the course of peer review. I believe that this data is important context for the FDA's consultation on the MRTP application for Swedish Match snus products. As you and Professor Glantz have drawn heavily on this study in your own consultation response,*
> *I think it important that you now disclose the relevant data for perceived harm of smoking. I await your response and disclosure with anticipation.*
> *Yours sincerely*
> *……*

Let's see how they respond. They don't seem to feel remotely accountable.

Population arguments used by UCSF

A final word on population effects. The UCSF argument for retaining the current warnings is really quite weird: is that being (a bit more) truthful about risks of snus use relative to smoking might cause snus use to increase if it provides reassurance to non-users, or means that people who might otherwise have quit continue to use the product because they don't think it is doing them much harm (even though that may be true). Of course, the much more likely outcome is a *beneficial* population effect, in which snus displaces smoking because its risks are better understood by smokers, and risks to any new snus users are so small that

they would be outweighed by benefits to switchers. For the balance to shift to net harm, completely implausible uptake of snus would be required by non-tobacco users. This counter argument is developed in the CASAA submission to the MRTP consultation, which I also recommend. This uses what is sometime referred to as the 'Risk-Use Equilibrium' argument as developed by Lynn Kozlowski in 2001 – it completely demolished Glantz's argument.

Uncertain population effects may be beneficial or harmful. There is a further subtlety. The difficulty with assessing population effects *before* the regulatory change that will create the population effects is that it is almost impossible to know with confidence what will actually happen. Neither is it possible to design studies that would provide meaningful insights, given how difficult it is to simulate the real world of perception formation. Creating impossible evidential demands is part of the game played by the anti-THR activists and it is the disreputable hand they are playing here. (It is like, for example, demanding proof of no long term health impacts for vaping). However, *in this case the uncertainty cuts both ways*. It is at least as likely that there will be a positive effect – as we have seen with snus in Scandinavia. So the Glantz suggestion of not allowing these warning changes because of uncertainty is at least as likely to have the harmful effect of foregoing positive benefits as more people use cigarettes and fewer use snus than would otherwise have been the case: analogous to the damage done by the snus ban in the EU. Should the regulator be cautious and not allow the change unless there is proof that it will not cause a population-level problem? *No, this isn't cautious*, because it puts at risk the potential and far more likely benefits.

Acting in the face of uncertainty. So given the regulator can either approve or reject the application, how should FDA address inherently uncertain population effects before they can measure them? The ethically legitimate way is to base regulatory determinations on *individual risk* and *in favour of truthful realistic communication.* That doesn't rule out negative population effects emerging, but given symmetrical uncertainty, it sets the right default options for a regulator – go with truth about individual risk and realistic communication. Then through market surveillance – as required by the MRTP – the option remains to take post-approval action if credible evidence emerges of adverse population effects, which is in my view highly unlikely.