Framing issues in evaluating a Modified Risk Tobacco Product application

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

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This contribution focuses on ethical and framing issues related to FDA-regulated risk communication. There are several key issues of principle that should inform the evaluation of the applicant's MRTP submission. I hope these are useful inputs to FDA's deliberations.

A 'materiality' test should apply to warning messages or warnings will be debased

It is not appropriate to ask any producer of any product to prove beyond reasonable doubt that there is *no risk* associated with use of its product. This is not a requirement for most products on sale in the United States or Europe. In fact many products do carry known risks, but do not carry warnings - fat, salt, high-heeled shoes, motorcycles, knives to name some obvious examples. The question is whether the risk is *material* to the extent that a special case should be made to warn about it on the packaging. This implies some sort of materiality or *de minimis* test should apply, so that the consumer is not continuously warned of trivial risks and so becomes desensitised to warnings about more serious risks. The evidence presented in the application suggests that the risks of mouth cancer, gum disease and tooth loss are either zero, close enough to negligible, or at least no greater than those normally tolerated in society without special treatment, to make a specific warning unnecessary and implicitly misleading. For this reason, the warnings related to mouth cancer, gum disease and tooth loss should be removed as the applicant requests.

Beyond merely true: the importance of proportionality and realistic comprehension

It is important that information provided to the public is true and evidence-based. However, being merely true is a *necessary but not sufficient* condition for an acceptable public risk communication. The message should also be framed in a way that means it is perceived by a reasonable person to be fair and proportionate. For example saying "*this product is not a safe alternative to smoking*" could be perceived as the product being 2% safer, 15% safer, 70% safer or 98-100% safer. If the reasonable consumer perceives anything but the last of these, then they will have been mislead by an incomplete representation of risk. The wording proposed by the applicant: "*No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes*", is much more likely to set a realistic perception, than the binary warning used at present. However, even this warning is unlikely to convey the two orders of magnitude difference in risk between snus use and smoking, meaning the proposal understates the risk reduction. So while the proposed warning is a very significant improvement it remains likely that regulated warnings, *as perceived*, continue to overstate risk and fail to provide Americans with a clear basis for informed choice.

The precautionary principle cannot apply

Some may argue that a 'precautionary approach' should be taken to allow for uncertainty, and that warnings should err on the side of overstating risks to anticipate future adverse findings. The precautionary principle is not applicable for this purpose. This because supposedly precautionary action may *in itself* be a cause of harm to human health. The most extreme example of this is the ban on snus in the European Union, other than Sweden. This was originally justified on a precautionary basis, but it has had the effect of denying most Europeans options to greatly reduce their personal risk from tobacco use and for most EU states to follow the significant declines seen in smoking prevalence where snus is available.

Warning messages should inform consumers not manipulate their behaviour

Messages should help consumers to make their own realistic decisions about risky behaviours, taking account of their own preferences and appetite for risk. Public authorities do not, for example, try to dissuade people from the dangerous activity of horse-riding, but it would be useful if people knew just how dangerous this activity can be in order to inform their own decisions. The same should apply to tobacco use: it is important that consumers know that smoking is an outlier in terms of health risk, but that consumption of snus creates health risks, if any, that are small or negligible in comparison.

Use of miscommunication of risk to purposefully modify behaviour is unethical

Public communication about risk should not exaggerate or understate risks, implicitly or explicitly, in order to pursue a behavioural outcome favoured by the state or a regulator, such as quitting all tobacco use in this case. The reason for this is that miscommunication of risk can have unintended consequences that may have lethal results. In this case, the most obvious risk is that someone will underestimate the reduction of risk in switching from smoking to snus, and as a result continue to smoke. It might be objected that miscommunication 'works' in that that it can lead to fewer people using a product like snus. But the difficulty arises when just one person has acted on state-sponsored miscommunication and continued to smoke instead of switching to snus. Ethically, it is more defensible to offer truthful and proportionate communication and to let people make their own decisions, even if those may not be what the regulator or public health authorities would like. The alternative of allowing wilful miscommunication to pursue a particular outcome is patronising and potentially lethal to those it misleads into the unintended course of continued smoking. *There is no ethical defence for knowingly misleading consumers*.

Regulatory hurdles to truthful communication will harm health

The most striking feature of the Swedish Match application is its length and depth. Suppose that instead of making this application, Swedish Match had judged that the costs of making the application outweighed the commercial or reputational benefits? If FDA is still unsatisfied even by this case, or offers some compromise wording, then maybe all companies simply will not judge it worthwhile to pursue MRTP applications. That may be true in the case of snus, but also for other nicotine products on the continuum of risk, including vapour products such as e-cigarettes or heat-not-burn tobacco vapour products. The danger of this arrangement is that whether the public receives truthful,

proportionate risk communication depends in the first instance on whether on a tobacco company judges that it is worthwhile.

Regulators have the responsibility (and liability) for realistic risk communication

It is a particular concern that FDA-approved risk communication to Americans actually relies on the commercial interest calculations of tobacco companies. For the risk communication to change, a tobacco company must make a lengthy MRTP application, and in doing so judge that the considerable costs and some risks are justified by the reputational or commercial advantage gained. The ethical dilemma for the FDA is that this system will leave in place a great deal of risk communication that is inappropriate and implicitly overstates risk, simply because tobacco companies have not judged it commercially worthwhile or practical to make an MRTP application. I respectfully submit that this arrangement does not serve the public interest well. It should be the responsibility of the *regulator or legislator* who is imposing these warnings, not tobacco industry executives, to ensure that risk communications are truthful, correctly understood and complete. It is important to recognise that there is no real dispute that that snus specifically and smokeless tobacco in general are far less risky than smoking, and that barriers to being truthful about that should be as low as possible. Four possible approaches, subject to having the necessary statutory mandate, could mitigate this:

- While FDA cannot change the legislation, it can encourage fair and proportionate risk communication by reducing the barriers - cost and procedural - to tobacco companies making MRTP applications for non-combustible products, and by using a 'light-touch' approach to evaluating applications.
- FDA could allow or encourage MRTP applications from third-parties acting in the public interest, both for specific products or that apply to whole categories.
- FDA itself could generate or encourage MRTP application to provide an evidence base for its risk communications.
- FDA can conduct or commission useful regulatory science on this issue. It should routinely monitor perceptions caused by mandatory risk communication to ensure these are aligned as far as possible with actual absolute and relative risk.

Generic versus specific applications - distortions of competition

A further concern is that only companies with substantial technical resources and market share will judge it worthwhile to incur the fixed cost of making MRTP applications, *and only for their own products*. It is also the case that Swedish Match products have been extensively studied in Europe but that studies of other manufacturers' products are less common, so there is far more evidence for it to draw on. The danger of this is that smaller companies selling very similar products - for example those complying with the Gothiatek standard used by Swedish Match - will have their products labelled with the default, but misleading, risk communication. The MRTP process may therefore become anti-competitive and work against innovation and entrants to the reduced risk nicotine products marketplace, as well as working against better health outcomes. On the other hand, if a manufacturer with the resources to make an MRTP application has to share the commercial benefits with competitors within the category through a generic change in warnings, then they will have reduced

incentives to make an MRTP application in the first place. FDA should consider a way of making specific applications apply generically, without diminishing the incentive to make an application in the first place. For example, FDA could judge whether extension of a specific application to a generic category is justified, but require companies wishing to use the changed warning to pay a royalty to the original MRTP applicant to recognise the value of the intellectual property in its application.

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.

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Declaration

Clive Bates runs Counterfactual, a public interest consulting and advocacy organisation focussed on a broad approach to sustainability, policy-making for the long term and good governance. Clive Bates has no competing interests with respect to tobacco, pharmaceutical, ENDS industries He was formerly a UK senior civil servant and Director of Action on Smoking and Health (London). He has been a long-term advocate of tobacco harm reduction[1] [2] [3] [4], supports the lifting of the European Union ban on snus, and wrote about the policy challenge of products like electronic cigarettes well before they were invented[5].

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