

TOBACCO CONTROL

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Editorial

Clearing the smoke or muddying the water?

After two years, 500 pages and thousands of person hours, the authors of the Institute of Medicine report on the science base for tobacco harm reduction must have been horrified by the headlines following the news conference (see box) launching their report.¹ (See executive summary on p 189.)

The Food and Drug Administration asked the Institute of Medicine four questions. The first three seek guidance on what happens when an individual uses a product or strategy for reducing harm—is there potential for a genuine health gain and how should this be evaluated? The fourth question addresses what happens to the population as a whole when harm reduction strategies are presented to smokers.

These questions are not simple, and largely untestable in advance of the widespread use of the products. The question about how the population as a whole will respond can never be answered in advance because it will depend on so many future unknowns—most notably the regulatory framework into which the products are actually launched and what marketing claims are actually permitted.

In this swamp of uncertainty and difficulty there also lurks the tobacco industry, especially Philip Morris, which sees its interests in “appropriate regulation” of reduced risk tobacco products.

It was hoped that the eagerly awaited report might address these questions and assist regulators and public health professionals to navigate through this treacherous terrain.

The report adopts three main themes: firstly, the authors lay out the evidence needed to provide assurance that “potential reduced exposure products” (PREPs) will actually reduce harm to the individual that switches from conventional smoking tobacco; secondly, the research and surveillance necessary to assess the population impact; and thirdly, the framework in which such products must be regulated.

The report addresses four questions, draws six conclusions, makes eight recommendations, and suggests

11 regulatory principles. I would like to offer six criticisms, which focus predominantly on the most influential aspects of the work: the summary and how it was presented to the media.

(1) *A muddle of a press launch*—The opening line of the press release² was: “Pharmaceutical and modified tobacco products designed to reduce the health risks of smoking cannot yet be proved to reduce tobacco-related disease”. This only signalled the start of confusing messages conveyed during the press conference. Is it that surprising that reporters took this as a criticism of proven smoking cessation treatments—nicotine replacement therapy (NRT) and bupropion? The headlines suggest that the authors had little faith in a product based harm reduction strategy, but in fact the report is much more positive: “Our committee applauds the notion of helping individuals who cannot or will not quit smoking. We believe that it may be possible to reduce harm from tobacco use with new products, but we frankly do not know the health effects of the various products on the market today that claim to do this”. In such a complex and controversial area, it is essential that great care go into communicating the concepts.

(2) *Too little disaggregation of PREPs into different categories*—There is a very great difference between the use of NRT in parallel to smoking as an alternative source of clean nicotine, and some novel tobacco product. However, both are classed as PREPs and discussed as if the same issues arise. The introduction of the former has negligible additional risks and abuse liability, whereas the latter could be a Pandora’s box of unforeseen harms. Pharmaceutical products must undergo a thorough and rigorous regulatory testing procedure set out by drugs regulatory agencies with significant regulatory hurdles on the way, whereas tobacco industry products have no or very little regulatory oversight. Buried in the report in chapter 4 is a comparison of two nicotine inhalers, Eclipse manufactured by RJ Reynolds and an inhaler manufactured by a pharmaceutical company. The comparison indicates that the projected abuse liability of Eclipse is high and that of the pharmaceutical inhaler low, contaminants are allowed in Eclipse but not the other, and Eclipse can be modified without regulatory oversight but not the pharmaceutical product. It is difficult to see how the regulatory principles set out would do anything to correct these regulatory imbalances. This blurring of these important distinctions was the source of some of the confusion at the press conference.

(3) *The complex question of risk communication was not adequately portrayed in the summary and press launch*—The authors do not envisage new reduced risk products being barred from the marketplace if the manufacturer does not make a health related claim (regulatory principle 7) and

Some of the headlines following the Institute of Medicine report launch

“Safer” cigarettes may be as harmful as regular varieties—Washington Post

“Safer” cigarettes no such thing, panel finds—Reuters

Panel questions tobacco therapies—Associated Press

Less tobacco may not mean less risk—CNN.com

No such thing as “safer” cigarettes—MSNBC

Is “cold turkey” the only safe way to quit smoking?—CBS HealthWatch-Medscape

marketing claims would require prior regulatory approval (principle 4). This implies that the main task facing regulators is to become arbiters of the validity of health claims for PREPs. This problem merely *starts* with assessing the scientific accuracy of a claim. Even completely accurate health related claims can be thoroughly misleading. Consider the phrase “Lower cancer risk than regular cigarettes”. Even if there is science to show this to be true it may have very different meaning to different individuals and be perceived in a way that is disproportionate. For smokers attempting to rationalise their behaviour, language like this can be a gift, albeit a poisonous gift. The questions arising in the societal management of PREPs are matters of communication and perception as much as science.

(4) *Excessive emphasis on market driven developments at the expense of mandatory performance standards*—The most straightforward place for regulators to start is to require all tobacco products to conform to certain standards—for example, a maximum nitrosamine concentration in the tobacco, or a threshold of, say 8 mg of carbon monoxide per milligram of nicotine in the tobacco smoke of manufactured tobacco products. This is acknowledged at regulatory principle 9, but not reflected in most of the discussion in the summary or report. The use of technical standards, applied across the board, leaves far less room for problematic marketing claims. It is also the exact opposite of the regulation that some within the tobacco industry are seeking. In their view of “appropriate regulation” the companies take the lead in product innovation, and regulators are there simply to try to endorse health claims made about the product, with the obvious effect of indemnifying the manufacturer. There are, for example, technical standards for maximum parts per million of mouse droppings in traded grain, but you will be unlikely to see much reference to low faeces flour emblazoned on a packet of cake mix.

(5) *Entrenching the status quo*—Regulatory principle 7 states that in the absence of any claim of reduced exposure or reduced risk, manufacturers of tobacco products should be permitted to market new products or modify existing products without prior approval of the regulatory agency after informing the agency of the composition of the product and certifying it would not increase risk. This marks an extraordinary concession—effectively accepting that the current generation of manufactured cigarettes is here to stay and outside the scope of regulation. Philip Morris must have been delighted about a regulatory framework that leaves Marlboro untouched, and gives official approval to a new range of reduced risk products. If regulatory interventions are taken as suggested in point 4 above, each existing product and new product would be subject to regulatory approval.

(6) *Insufficient analysis of how to act in the face of uncertainty and incomplete evidence*—The report places very substantial evidential requirement on those seeking to bring PREPs to the market with a health related claim. The

easiest approach for the public health and regulatory community is to demand near complete certainty before approving the marketing of any PREPs. At first sight this appears prudent, but it is actually a *transfer* of risk from the regulator to the smoker. With insurmountable evidential hurdles in place, the regulator may sleep easy in a cocoon of professional scepticism. A self protecting regulator finds it easy to say “no” to developments that might reduce harm to smokers. This is because regulators are not blamed for the harm that smoking causes, but would be blamed for any adverse consequences arising from a PREP they approve. With many in the public health community chastened by the experience of “light” cigarettes, the effect of such regulatory asymmetry could be to keep reduced harm products off the market, guarantee the market to the most harmful form of nicotine delivery, and potentially lead to many otherwise avoidable deaths. Regulators and the public health community tend to wash their hands of the health consequences of *not* allowing harm reducing approaches into the marketplace. While I do not wish to see a rush of novel tobacco products making health claims, there are immediate real problems arising from the “self serving caution” of regulators. For example, this applies to the refusal of some regulators to approve harm reduction indications for pharmaceutical NRT, the regulatory barriers facing a nicotine gum manufacturer that wants to compete directly with cigarettes as a supplier of lifestyle branded nicotine, and the clumsy regulation of certain oral tobaccos that have substantially lower health risks than cigarettes.

Missing from the coverage was any sense that there are practical harm reducing measures that can be taken without giving away the entire field to Philip Morris. It is possible to authorise NRT products for harm reduction applications, and it is possible to allow nicotine gum to compete with cigarettes, as principle 11 implies. In my opinion, there can be little objection to a requirement that all tobacco placed on the market to be low in nitrosamines—even if the exact health benefit is impossible to determine at this stage?

Having said all that, one should not be unduly negative. The report provides a first rate review of the literature and important insights into the numerous difficulties, and the summary and press coverage did not do it justice. I would urge readers to read the full report and use it as a starting point for debate. Please make your views known on *eTC*!

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1 Institute of Medicine. *Clearing the smoke: the science base for tobacco harm reduction*. Washington DC: Institute of Medicine/National Academy Press, 2001. <http://www.nap.edu/books/0309072824/html/>

2 Institute of Medicine. *Health effects of modified tobacco products uncertain; greater scrutiny needed*. Washington DC: Institute of Medicine, National Academy of Science, 22 February 2001. <http://www4.nationalacademies.org/news.nsf/isbn/0309072824?OpenDocument>