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Potential reduced exposure products

## The time for tobacco industry sponsored PREP evaluation has arrived

T Eissenberg

Rigorous and objective industry funded evaluation of potential reduced exposure products will require innovation and flexibility, but must begin now

Potential reduced exposure products (PREPs) for smokers are marketed by the tobacco industry as a way for smokers to reduce toxicant intake while continuing to use tobacco.<sup>1</sup> In the past, similarly marketed products, so called "low yield" cigarettes, were financial successes but public health failures.<sup>1,2</sup> Deceptive marketing of these early PREPs helps to explain their financial success,<sup>3</sup> while a lack of objective pre-market evaluation of users' smoke toxicant exposure helps to explain their public health failure.<sup>1,4</sup> Given this history, anyone interested in public health is correct to be sceptical of the marketing that surrounds a new generation of PREPs in the USA (for example, Accord<sup>®</sup>, Advance<sup>™</sup>, Aeros<sup>®</sup>, Eclipse<sup>®</sup>, Quest<sup>®</sup>) and Europe (for example, NicStic<sup>®</sup>). Even more important, public health advocates are correct to insist that PREPs be evaluated comprehensively, rigorously, and objectively.<sup>1,5</sup> This type of evaluation will help ensure that policymakers and consumers are as knowledgeable as possible regarding whether or not these products increase, decrease, or fail to change smokers' toxicant exposure and cessation rates, as well as tobacco use initiation rates among non-smokers. Of course, comprehensive evaluation will be costly, and the industry that develops the PREPs, and stands to profit from them, must pay for that evaluation. However, given the tobacco industry's history of suppressing scientific results obtained within its walls,<sup>6,7</sup> objective evaluation is best left to independent researchers. Tobacco industry support for objective work completed by independent researchers may seem challenging, but the expertise exists and the need is real.

Over the last few years, I and several other independent researchers have been working to develop methods for PREP evaluation.<sup>8-15</sup> With funding from the US National Institutes of Health, we continue to refine our methods for evaluating smokers' toxicant exposure when they use PREPs, and for determining

how PREP availability influences smokers' choice to make a quit attempt. Where methods for evaluating the public health effects of commercial products do not exist, method development is an appropriate use of public funds, now and in the future. However, once the methods are developed and validated, the financial burden of evaluating the putative exposure reduction associated with individual products should shift to the industry.

### DILEMMA

Industry support for product evaluation is a dilemma for those of us who have worked to develop the methods to evaluate PREP effects. On the one side, we learned from previous experience that PREP marketing without evaluation profits the industry and kills smokers.<sup>1,4,16</sup> With this history in mind, many public health advocates now call for objective PREP evaluation.<sup>1,5,8,17</sup> On the other side, tobacco industry funding of work completed by non-industry scientists is, at best, a controversial topic.<sup>18-21</sup> Researchers who accept tobacco industry dollars risk losing access to other funding sources, cannot publish that work in some journals, and may find their objectivity and integrity questioned. All of these outcomes are at least a partial result of the tobacco industry's documented history of scientific misconduct.<sup>22</sup> Thus, evaluation of specific PREPs, rightly funded by the tobacco industry, and likely to provide significant public health benefit (for example, by alerting policymakers and consumers when PREPs increase or do not change the health risks of smoking<sup>8,23</sup>), may be suppressed because few independent researchers will perform the work.

### SELF EXAMINATION

With regard to PREP evaluation, the public health community might benefit from careful self examination of underlying beliefs and assumptions. For some, firmly held beliefs posit that PREPs cannot reduce tobacco caused disability,

disease, and death. However, the effects of PREPs on disease risk can and have been demonstrated empirically (that is, epidemiological studies that suggest that "low yield" cigarettes did not decrease cigarette-caused disease rates appreciably<sup>4</sup>) and the toxicant exposure associated with use of a particular PREP can be tested in the clinical laboratory now.<sup>8-10,12</sup> Using a belief as the basis for ignoring a testable approach is unscientific, and therefore should be unacceptable to all who value empirically based public health policy. For others, PREPs are assumed to be industry public relations ploys, and are not legitimate topics for scientific evaluation. The popularity of past PREPs (that is, "low yield" cigarettes), the "public health disaster"<sup>2</sup> of failing to evaluate their purported exposure reduction in a timely manner, and the vast monetary rewards future PREPs may represent for the industry<sup>24</sup> makes avoiding PREP evaluation ethically untenable.<sup>25</sup> Equally untenable, though, is a call for industry funded objective PREP evaluation that is coupled with the refusal of tobacco industry support. Many who favour PREP evaluation recognise that the industry must pay the price, but worry about the hypocrisy of demanding work that we will not do, and payment that we will not accept.

### OBJECTIVE EVALUATION

Rigorous and objective industry funded PREP evaluation is a complex issue that will require innovation and flexibility. At the least, work must be completed in an atmosphere of openness and transparency, with financial arrangements and scientific methods accessible to all. Evaluation studies must be designed, conducted, and reported without industry oversight, and researchers must retain ownership of their data. Data safety monitoring boards may be used to ensure that results are reported accurately and that conclusions can be supported by the data. Eventually, government may play a key role by mandating specific evaluations, managing a competitive process for awarding industry funded contracts, using industry funds to support expert review of pre-market testing procedures and results, limiting marketing based on evaluation, and requiring detailed post-marketing surveillance.<sup>1,5</sup>

The time for industry sponsored evaluation of the exposure reduction associated with specific PREPs has arrived, even while these and other PREP evaluation methods are being refined and improved. I ask for all researchers with expertise in PREP evaluation to help engage the broader public health community in a unified approach that

ensures this important work is conducted:

- in an environment where industry support for PREP evaluation is accepted only under specific, clearly articulated conditions
- by qualified, objective researchers using state of the art techniques
- with oversight that maintains the integrity of the research enterprise, from study design to data analysis, to timely publication.

Failure to act in this manner will, at best, leave evaluation in the hands of an industry with a poor track record for objectivity. At worst, failure to act will doom us to repeat the very history that we remember too well: a history where uninformed consumers and many public health advocates<sup>26</sup> embraced untested products that enriched the tobacco industry but did not reduce smokers' exposure to lethal smoke toxicants.

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