Rethinking U.S. tobacco and nicotine regulation (part 1)

written by Clive Bates | 1 October 2022

Here is a proposal to reshape U.S. regulation of reduced-risk tobacco products:

A science-based regulatory framework for implementing tobacco harm reduction should conform to the following 11 principles:

1. Manufacturers of tobacco products, whether conventional or modified, should be required to obtain quantitative analytical data on the ingredients of each of their products and to disclose such information to the regulatory agency.
2. All tobacco products should be assessed for yields of nicotine and other tobacco toxicants according to a method that reflects actual circumstances of human consumption; when necessary to support claims, human exposure to various constituents of tobacco smoke should be

assessed using appropriate biomarkers. Accurate information regarding yield range and human exposure should be communicated to consumers in terms that are understandable and not misleading.

3. Manufacturers of all potential reduced exposure products should be required to conduct appropriate toxicological testing in preclinical laboratory and animal models and appropriate clinical testing in humans to support the health-related claims associated with each product and to disclose the results of such testing to the regulatory agency.
4. Manufacturers should be permitted to market tobacco-related products with exposure reduction or risk reduction claims only after agency approval based on scientific evidence (a) that the product substantially reduces exposure to one or more tobacco toxicants and (b) if a risk reduction claim is made, that the product can reasonably be expected to reduce the risk of one or more specific diseases or other adverse health effects, compared with whatever benchmark product the agency requires to be stated in the labeling. The "substantial reduction" in exposure should be sufficiently large that independent scientific experts would anticipate finding a measurable reduction in morbidity and/or mortality in subsequent clinical or epidemiological studies.
5. The labeling, advertising, and promotion of all tobacco-related products with exposure reduction or risk reduction claims must be carefully regulated under a "not false or misleading" standard, with the burden of proof for the claim resting on the manufacturer not the government. The responsible agency should have the authority and resources to conduct surveys of consumer perceptions relating to these claims.
6. The regulatory agency should be empowered to require manufacturers of all products marketed with claims of reduced risk of tobacco-related disease to conduct post-marketing surveillance and epidemiological studies as necessary to determine the short-term behavioral and long-term health consequences of using their products and to permit continuing review of the accuracy of their claims.
7. 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 that the product could not reasonably be expected to increase the risk of cancer, heart disease, pulmonary disease, adverse

reproductive effects, or other adverse health effects, compared to similar conventional tobacco products, as judged on the basis of the most current toxicological and epidemiological information.

8. All added ingredients in tobacco products, including those already on the market, should be reported to the agency and be subject to a comprehensive toxicological review.
9. The regulatory agency should be empowered to set performance standards (e.g., maximum levels of toxicants; definitions of terms such as "low tar") for all tobacco products, whether conventional or modified, or for classes of products.
10. The regulatory agency should have enforcement powers commensurate with its public health mission, including the power to issue subpoenas.
11. Exposure reduction and risk reduction claims for drugs and devices that are supported by appropriate scientific and clinical evidence should be allowed by the FDA

What is this work of regulatory voodoo?

Could this be a better way than what we have now? It could hardly be worse. I particularly like Principle 7. This seems to grant a presumption of access to the market for safer products.

Where does it come from?

Wise old hands will know this is a trick question. Principles 1-11 are lifted directly from the groundbreaking 2001 Institute of Medicine report, Clearing the Smoke: assessing the science base for tobacco harm reduction. These principles are drawn from Chapter 7: Implementation of a Science-Based Policy of Harm Reduction.

The Institute of Medicine is now the National Academies of Sciences, Engineering, and Medicine – NASEM)

The point is that this was a major exercise commissioned by FDA to inform legislation for tobacco harm reduction. It was probably cautious, as this period coincided with revelations that "light" and "mild" cigarettes, while implicitly marketed as safer than conventional cigarettes, were not, in fact, safer.

Coming soon

In part 2 of this post (May 2023), I will make some specific suggestions for how today's FDA could adapt its regulatory regime for reduced-risk products to make its system more efficient, transparent and predictable – with better results for public health.

Your ideas, please

If you are engaged as a vape industry professional, consumer or public health advocate, and you have a view on how FDA could do better within the existing law, please share your thoughts in the comments so I can appropriate your ideas. You can comment anonymously.