New report identifies research needed on 'modified risk' tobacco products

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A new Institute of Medicine report specifies the types of research that the Food and Drug Administration should require before allowing tobacco companies to sell or advertise 'modified risk' tobacco products as being capable of reducing the health risks of tobacco use. While modified risk tobacco products could be one part of a comprehensive strategy to lower tobacco-related death and disease in the U.S., especially among tobacco users who are unable or unwilling to quit entirely, little is currently known about the products' health effects and whether they pose less risk than traditional tobacco products. Examples of modified risk tobacco products may include e-cigarettes and tobacco lozenges.

Companies and other sponsors developing modified risk tobacco products should consider using FDA-approved independent third parties to oversee health and safety research on their products, adds the report, which was completed to fulfill a congressional mandate. Independent oversight would ensure that the data submitted to FDA are reliable and credible, and it could help re-engage the mainstream scientific community in research. Because of the tobacco industry's well-documented history of improper conduct, many institutions and scientists currently refuse to conduct or publish research supported by the tobacco industry.

"Right now there's a shortage of scientific evidence on the health effects of modified risk tobacco products, and the tobacco industry currently lacks the trustworthiness, expertise, and infrastructure to produce it," said Jane Henney, chair of the committee that wrote the report, and professor of medicine and public health sciences at the University of Cincinnati. "Having trusted third parties oversee the conduct of research could help re-engage scientists and enable generation of credible research data on the health effects of these products."

The Family Smoking Prevention and Tobacco Control Act of 2009 requires that modified-risk tobacco products undergo a pre-market approval process similar to drugs and devices. According to the act, a company that wants to market a lower risk tobacco product in the U.S. must offer scientific proof to FDA that the marketing of the product will not only reduce harm to individual users, but also benefit the health of the population as a whole. The act also directed FDA to consult with IOM on how scientific studies of modified risk tobacco products should be designed and conducted.

The IOM's report says that the studies should examine all of the areas needed to forecast and monitor a proposed product's impact on public health, including its composition and addiction potential; the amount of human exposure to harmful components; perceptions about the product's effects and likelihood of addiction; and effects on human health. Studies should be generalizable to the whole population and should also include populations of special relevance, including current and former smokers, beginning smokers, adolescents, and populations at high risk for tobacco use.

While studies submitted to FDA to demonstrate products' safety are usually conducted or sponsored by the companies themselves, the tobacco industry at present lacks the capacity and expertise to conduct such research, the report says. The industry's history of improper manipulation of data undermined the credibility of its research and left it isolated from the mainstream scientific community. Many major universities have policies against acceptance of tobacco funding, for example, and many high-impact scientific and medical journals will not accept manuscripts supported by the tobacco industry.

Using independent, FDA-approved third parties to conduct, provide oversight of, and distribute funding for research could distance the influence and

reputation of the tobacco industry from the scientists who are researching their products. Examples of third-party partnerships between industry and government include the Health Effects Institute and the Reagan-Udall Foundation. No similar organization currently exists for the tobacco industry.

Making data publicly available will also build public trust and will allow for independent analysis of data and methods, the report says. FDA should require sponsors of modified risk tobacco products to place all data generated during a product's development and marketing in a public repository selected by the agency.

FDA should also require that studies offered in support of an application to market modified risk tobacco products conform to established standards of good research governance, including appropriately qualified investigators, transparency, independent institutional review board or ethical review, and adherence to federal regulations that ensure the protection of human participants in biomedical research.

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