GTNF 2016
Brussels
Sept. 27-29
Session 5: Risk continuum vs. risk cliff

Recent studies suggest that, with the advent of e-cigarettes and other reduced-risk products (RRPs), the theory of the continuum of risk of tobacco products should be replaced with the model of a risk cliff. According to scientific findings, the main culprit is not nicotine but the delivery system, and the differences between delivering nicotine through burning tobacco leaves and delivering nicotine through an aerosol are immense.

Hence, instead of the gradation from combustible cigarettes over heated-tobacco products to low-toxicant smokeless tobacco, e-cigarettes and, at the end of the range, licensed medical products as known from the risk continuum hypothesis, the risk cliff theory would have combustible tobacco products, the smoke of which is much more complex than the aerosol of an e-cigarette, for example, on one side, and all RRPs, united by their significantly reduced exposure to toxicants, bundled on the opposite side.

In vitro testing of e-cigarettes jointly carried out by the two leading international cigarette manufacturers has shown that aerosols don't cause any oxidative stress, and toxicity is reduced. Recent statements by institutions such as Public Health England and the U.K.'s Royal College of Physicians and a briefing by Action on Smoking and Health imply that there is a growing consensus, at least in the U.K., on the harm reduction potential of e-cigarettes.

In the U.S., the Food and Drug Administration (FDA), which has regulatory oversight of tobacco products, takes a different approach. The FDA provides no "category" approval, per se, but makes product-specific decisions based on scientific evidence.

To assess the individual risk of a product, it needs to be assessed whether the product reduces a smoker's risk of harm and whether its effect is similar to cessation. However, only little data is available to date regarding the comparative reductions in biomarkers of exposure compared to smoking abstinence. In addition, the product's potential to benefit public health is considered: Do smokers switch fully or predominantly to the product? Do nonsmokers take up the product in large numbers?

Generally, the FDA is not proactive in communicating product risk. While the agency seems to acknowledge the risk continuum concept, it is reluctant to populate the theory with other products. That products pending regulatory action are not placed in a risk continuum is understandable, but even products that have received premarket tobacco product application orders—to date only one, Swedish Match's General snus—do not appear there.

Next to the risk continuum and risk cliff theory, a third approach speaks of risk categories, attempting a "risk bucket" classification, with combustible products in the first, cleaner nicotine products, such as e-cigarettes, in the second, and no-harm products in the third basket. Its main goals should be harm minimization and benefit maximization to reduce the death and disease burden.

Perhaps more interesting than abstract models, however, is the consumer perception of the risk continuum, which is being distorted by politicians promoting total abstinence and helped by an often symbiotic relationship between public health and journalists, as one panelist termed it. Different marketing strategies of novel products, he said, such as that of Philip Morris International's iQOS, which seems to draw from the Marlboro success, and the different approach of British American Tobacco in marketing Vype, are indicative of how much confidence the industry has in the category.