Editorial

Brave New World in Tobacco Product Design

Commentary re: J. L. Pauly *et al.*, Glass Fiber Contamination of Cigarette Filters: An Additional Health Risk to the Smoker? Cancer Epidemiol. Biomark. Prev., *7:* 967–979, 1998

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Tobacco product manufacturers keep trying. Since the 1950s, they have repeatedly sought to wrap their products in the appearance of reduced risk, if not health protection (1). First, it was "king-size" length, and then filters. One of the most prominent of the early filter brands (Kent) used crocidolite as the filtering agent (2). After filters lost their charm, "low tar" was the selling point, although the claims ignored how people actually smoke (3). By 1968, scientists at Brown and Williamson and British American Tobacco knew low tar was a sham, calling these brands mere "health-image" smokes in private (4). Today, cigars are marketed in ways that minimize health concerns (5), and both Philip Morris and R J Reynolds are introducing novel, high-tech tobacco products (Accord and Eclipse).

The approaches both companies have taken with these products suggest that they would like to be able to make health claims for them.

Both companies have openly presented chemical and toxicological data on their novel products in scientific forums (6, 7), and both companies have advocated for a special category of regulation for what they have called "reduced risk" tobacco products under the FDA[2] (8).

The FDA is the appropriate place for such potential claims to be examined and considered. As discussed in detail elsewhere (9), when the FDA considers whether to permit health claims for such products it should consider not only how such products might affect those who are unable to stop smoking, but also those who would, but for the novel product, stop using tobacco products altogether, as well as those who have not yet started. Moreover, it is clear that, even with the best of plans and intentions, things can go wrong. After a product such as this is given a conditional approval for marketing, its effect on the public health should be monitored in an ongoing fashion and changes made in its regulation (including removal from the market) if it does not provide a clear, net public health benefit. Unfortunately, if Congress passes legislation that limits the FDA's power to regulate tobacco products, it may well turn out that the agency will, in the end, lack this essential flexibility.

Elsewhere in this issue, Pauly *et al.* demonstrate that the mouthpiece of Eclipse is contaminated with glass fibers from an insulation mat integral to each Eclipse (10). Glass fibers are regarded as carcinogens, and the fibers on the Eclipse mouthpiece may be respirable. If this phenomenon poses a risk to consumers, it would seem to be at odds with a design philosophy articulated by an RJR scientist that health hazards not found in conventional products should not be included at all in novel tobacco products such as Eclipse (J. Donald deBethizy, personal communication, September 1998).

The observations of Pauly and his colleagues raise precisely the sort of question which the FDA addresses all of the time in the conduct of its usual business with other products. It is time that the agency deals with issues such as this in regards to tobacco products.

For the foreseeable future, tens of millions of Americans will continue to ingest nicotine regularly. While the cigarette companies have long enjoyed a virtual monopoly on nicotine maintenance with their conventional products, other forms of nicotine delivery can, and likely should, compete more directly (11). At a minimum, products such as Eclipse should be given careful regulatory scrutiny as they attempt to enter the market as less hazardous alternatives to conventional cigarettes. While it is unlikely that there will ever be genuinely "equal" regulation of tobacco products and nicotine-delivering medicines, there can and should be "co-regulation," in which FDA regulates each category of product with thoughtful, ongoing consideration of how it is regulating the other (12). Such an approach can respect the historical differences between the two categories while keeping the potential for public health benefit the uppermost consideration.

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[2] The abbreviation used is: FDA, Food and Drug Administration.

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