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The **Food and Drug Administration** (FDA) Proposed Rule: **Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Extension of Comment Period**

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The Lega Italiana AntiFumo (LIAF – Italian Antismoking League) feels morally compelled to comment on FDA deeming regulation, because of its mission of spreading the "culture of not smoking". LIAF is currently in support of alternative products that do not require the combustion of tobacco, such as electronic cigarettes (ECs), because of their tobacco harm reduction potential.

ECs are simple yet revolutionary products for tobacco harm reduction. Although they emit vapor, which resembles smoke, there is no tobacco and no combustion involved in EC use, therefore regular users may avoid several harmful toxic chemicals that are typically present in the smoke of tobacco cigarettes.

Existing evidence indicates that EC use is by far a less harmful alternative to smoking. Although some toxic chemicals are released in the EC vapor, their levels are of order of magnitude lower compared to tobacco smoke.

Surveys, clinical, chemical and toxicological data have been often misrepresented or misinterpreted by health authorities and tobacco regulators, in a way that the potential for harmful consequences of EC use has been largely exaggerated. It is obvious that some residual risk associated with EC use may be present, but this is probably trivial compared to the devastating consequences of smoking. Moreover, ECs are used by smokers as a substitute for conventional cigarettes or by former smokers as to prevent smoking relapse; thus, any risk should be estimated in relation to the risk of continuing or relapsing to smoking.

Clearly, LIAF feels that more research is needed in several key areas (e.g. atomizer design and materials to further reduce toxic emissions, or ingredients' toxicology to determine the relative risk of flavorings by inhalation) and that regulations should simply aim at minimizing penetration of EC use in non-smokers and youngsters, and ensure that consumers are buying products that meets high quality and safety standards.

However, any regulatory decisions should not compromise the variability of choices for consumers and should make sure that ECs are more easily accessible compared to their main competitor, the tobacco cigarettes. Consumers deserve and should make informed decisions, and research will definitely promote this. In particular, LIAF believes that current data on safety evaluation and risk assessment of ECs are sufficient enough to avert restric¬tive regulatory measures as a consequence of an irrational application of the precau¬tionary principle.

Here we enclose a critical appraisal of a total of 107 studies investigating existing laboratory and clinical research on the potential risks from electronic cigarette use, compared to the well-established devastating effects of smoking tobacco cigarettes. We hope the FDA will find this document useful in refining their deeming regulations of e-cigarettes.

Yours faithfully,

Prof. Riccardo Polosa (1)
LIAF Chief Scientific Advisor

Notes:
(1) Riccardo Polosa, Professor of Internal Medicine at the University of Catania is ranked by BMC Public Health journal as the most productive and influential authority on e-cigarettes. See table 6 in:
http://www.biomedcentral.com/content/pdf/1471-2458-14-667.pdf

Financial & competing interests disclosure
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fees and research funding from manufacturers of stop smoking medications including GlaxoSmithKline and Pfizer. He has also served as a consultant for Pfizer and Arbi Group Srl (Milano, Italy), the distributor of Categoria™ e-Cigarettes. R.P.'s research on electronic cigarettes is currently supported by LIAF (Lega Italiana AntiFumo)

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