UNIVERSITÀ degli STUDI di CATANIA

LEGA ITALIANA ANTI FUMO

7 July 2015

To:
Mr. Gan Kim Yong, Minister for Health, Singapore
Mr. Zee Yoong Kang - Chief Executive Officer of Health Promotion Board, Singapore
Dr. Mimi Choong - Chief Executive Officer of Health Sciences Authority, Singapore

Dear Mr. Gan, Mr. Zee and Dr. Choong,

My name is Riccardo Polosa, and I am the Director of the Centre for Tobacco Prevention and Dependence Treatment, at the University of Catania (Italy) and Honorary Professor of Medicine at the University of Southampton (United Kingdom). I am writing in relation to your Ministry's recent announcement of a significant extension to Singapore's tobacco control program that seeks to ban a range of tobacco and nicotine products from December this year.

As one of the leading researchers on novel nicotine products, I believe there is compelling scientific evidence that shows that potentially safer alternatives to cigarettes can be beneficial from the public health perspective. In that context, I believe Singapore's tobacco control policies deserve a thorough re-think to ensure any regulations are based on state-of-the-art science, which is rapidly evolving. Tobacco harm reduction strategies should complement existing tobacco control efforts as rightly pointed out by Dr. Fatimah Lateef in the Parliament in the 2010 debate on alternative tobacco products. I strongly encourage the Ministry to re-visit the debate and am prepared to share with you in more detail my research on this subject and discuss research priorities that could ensure that the potential public health benefit of new alternatives to cigarettes is maximized while any potential risks are minimized.

As Scientific Director of LIAF (translated acronym for the Italian No Smoking Association), I have dedicated many years of my clinical and research activity to fight against tobacco smoking. I am the author of more than 550 scientific publications, 330 of which are peer-reviewed articles and book chapters relating to respiratory medicine, clinical immunology, tobacco addiction, and tobacco harm reduction. I have led several clinical trials on alternative products to tobacco smoking, including electronic cigarettes, and in 2014, I was identified as the most prolific academic author in the field of e-cigarettes. (See Zyoud, S.H., *et al.*, *Worldwide research productivity in the field of electronic cigarette: a bibliometric analysis*, BMC Public Health 2014).

When I first started investigating these products in late 2009, I was myself quite skeptical about their potential and I even discouraged their use without knowing very much about them. But I quickly changed my opinion when I found that many smokers using these products were quitting for good and felt much better in health and spirit. It was such a rewarding experience to have them thanking me for having won the most important battle of their life. Since then I have been working with great

enthusiasm to evaluate in more detail these products, determined to understand how to maximize their beneficial effects. I am now convinced that more effective approaches are needed to reduce the disease burden of tobacco smoking. E-cigarettes and other novel products are a recent development and represent an opportunity to improve globally the health of millions of smokers by reducing the burden of smoking-related diseases.

With any emerging behavior associated with exposure to inhalational agents, there is legitimate cause for concern and a need for study of potential harm. However, this potential risk must be taken in context of known harm of cigarette smoking in individuals who are already smoking. Indeed - under normal conditions of use - vapour toxicology is by far less problematic than that of conventional cigarettes (1), e-vapor products are at least 95% less harmful compared to combustible cigarettes (2) and exclusive ECs users have significantly lower urine levels of tobacco smoke toxicants and carcinogens compared to cigarette smokers (3).

In addition, e-cigarettes are used almost entirely by smokers and former smokers who switch from cigarettes, while the use among never smokers and minors is negligible with no gateway effect documented to date (4,5). Last but not least, there is now emerging evidence that substituting smoking with regular e-cigarette use may produce significant respiratory health gains in "healthy" smokers as well as in asthmatic smokers (6).

Consequently, many jurisdictions, most prominently the United States and the European Union, chose not to ban e-cigarettes or regulate them as medicines but rather to regulate them as alternatives to cigarettes and other burned tobacco products.

In the EU, e-cigarettes will be regulated under the new Tobacco Product Directive (2014/40/EU) that requires, among other things:

- Notification when an e-cigarette is intended to be placed on the market;
- Mandatory safety and quality standards for nicotine content, ingredients and devices as well as refill mechanisms;
- Obligatory consumer information leaflets;
- Restrictions on advertising; and
- A system to monitor adverse effects of e-cigarettes.

In the United States, the US Food and Drug Administration (FDA) proposed a new rule that would extend the agency's tobacco authority to cover e-cigarettes. In the proposal, the FDA states that "*[e]merging technologies such as the e-cigarette may have the potential to reduce the death and disease toll from overall tobacco product use depending on who uses the products and how they are used."*(7)

Under the proposed rule, e-cigarette manufacturers would be, among other things, required to:

- Register with the FDA and report product and ingredient listings;
- Only market new products after FDA review;
- Only make direct and implied claims of reduced risk if the FDA confirms that scientific evidence supports the claim and that marketing the product will benefit public health as a whole. In addition, under the proposed rule, e-cigarettes would be required to carry a health warnings and their sale to minors would be prohibited.

In conclusion, e-cigarettes and other alternative tobacco products that can reduce smoking-related risks are an opportunity not to be missed. I would be very happy to discuss with you the research and the evolving evidence on e-cigarettes in more detail.

Please do not hesitate to contact me if you need more clarification or information.

Yours sincerely,

Prof. Riccardo Polosa
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LIAF Chief Scientific Advisor
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