

Honourable Commissioner of Health and Food Safety  
Stella Kyriakides  
Rue de la Loi / Wetstraat 200  
1049 Brussels  
Belgium

Dear Honourable Commissioner Stella Kyriakides

We are a group of scientists and clinicians that would like to bring an important topic on improving the public health of EU citizens to your attention. As a group of public health leaders and academics with an interest in harm reduction we are writing to you in order to help reduce the health burden from smoking.

It is widely recognized that smoking is the cause of serious health diseases both in smokers and people indirectly exposed to smoking emission. A growing number of scientific bodies recognize a role that alternative nicotine-based product can play in reducing population harm caused by the smoking products, even though all nicotine-based products have some residual risk for the individual user. More recently, in a brief on the Electronic nicotine and non-nicotine delivery systems (EN&NNDS), the WHO emphasized that *“There is conclusive evidence that completely substituting EN&NNDS for combustible tobacco cigarettes reduces users’ exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes”*.<sup>1</sup>

For these reasons, we followed with great interest the work made by the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) on electronic cigarettes: today it is estimated that more than 12 million people in Europe (EU27 + UK) use electronic cigarettes, but in most of the cases they are not completely aware of the health impact of electronic cigarettes, in particular when compared with smoking products like cigarettes. This evidence is clearly shown in the recently issued Special Eurobarometer 506 “Attitudes of Europeans towards tobacco and electronic cigarettes”<sup>2</sup>, which reports that only 37% of respondents believed that vaping was less harmful than tobacco products<sup>3</sup>.

However, the SCHEER was mandate by the European Commission to focus only on health impacts of electronic cigarettes compared to non-smoking<sup>4</sup>. As a result, the SCHEER Final Opinion on electronic cigarettes leaves the users of electronic cigarette without guidance and clear information about the level of risk of these products compared to traditional cigarettes. Without clear information on the relative risk associated to the electronic cigarettes, users of electronic cigarettes may be led to the wrong conclusion that electronic cigarettes are as harmful as traditional cigarettes and so go back to smoking cigarettes.

As stated above, clearly electronic cigarettes are not risk-free. However, as also found by the recently issued Cochrane review, electronic cigarettes have helped smokers to stay away from

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<sup>1</sup> [Electronic-nicotine-and-non-nicotine-delivery-systems-brief-eng.pdf \(who.int\)](#)

<sup>2</sup> Eurobarometer 506: <https://op.europa.eu/en/publication-detail/-/publication/c070c04c-6788-11eb-aeb5-01aa75ed71a1/language-en/format-PDF/source-search>

<sup>3</sup> Eurobarometer 506, page 122

<sup>4</sup> [scheer\\_o\\_017.pdf \(europa.eu\)](#), page 6

cigarettes<sup>5</sup>. This comes with a net public health benefit as electronic cigarettes, along the continuum of risk, are less harmful than cigarettes and other combusted products.<sup>6</sup>

This approach was taken by Public Health England in its report entitled “E-cigarettes: an evidence update”<sup>7</sup>, where researchers from King’s College London, the UK Centre for Tobacco & Alcohol Studies and the Queen Mary, University of London found that vaping may not be 100% safe, most of the chemicals causing smoking-related disease are absent and the chemicals which are present pose limited danger. It has been previously estimated that EC [electronic cigarettes] are around 95% safer than smoking<sup>8</sup>. This appears to remain a reasonable estimate. This approach has proven to be successful: today UK is the country, right after Sweden, with the lowest smoking prevalence in Europe (12% and Sweden 7%, compared with the EU average of 23%)<sup>9</sup>.

Recently also French health authorities have adopted a clear communication to smokers on electronic cigarettes. The Santé Publique France’s Tabac Info Service suggests smokers to use electronic cigarette “*without having risks for your health in the short term*” and “*based on current scientific knowledge, it seems that vaping is less dangerous for health than smoking*”<sup>10</sup>.

Also, from this perspective, the Final SCHEER Opinion added to the confusion, since it did not provide any answer, nor indication about a risk of e-cigarettes compared to smoking.

Taking the above into consideration, we would like to ask the European Commission and SCHEER to initiate as soon as possible a second scientific opinion on electronic cigarettes to examine the relative risk-profile versus continued smoking.

Europe needs to have a full and complete discussion on electronic cigarettes and, more in general, around all alternative nicotine-delivery systems. But this discussion needs to be based on up-to-date scientific assessment. There’s no other way than continue finding all potential ways to help smokers who for any reason are not willing or unable to quit their nicotine addiction. Not only smokers but also general public expects scientists, SCHEER and the European Commission to provide them with a comprehensive evaluation of the risks. A second or complimentary mandate to the SCHEER on the relative risk of e-cigarettes compared to continued smoking is thus a logical next step to complete the current evaluation and provide consumers and current smokers with accurate information.

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<sup>5</sup> Cochrane review entitled “Electronic cigarettes for smoking cessation” pointed out that “There was moderate-certainty evidence that EC with nicotine increased quit rates at six months or longer compared to non-nicotine EC and compared to NRT”. (October 2020).

<sup>6</sup> Stephens, Comparing the cancer potencies of emissions from vapourised nicotine products including e-cigarettes with those of tobacco smoke <https://tobaccocontrol.bmj.com/content/27/1/10>, W. Stephens

<sup>7</sup>[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/733022/E-cigarettes\\_an\\_evidence\\_update\\_A\\_report\\_commissioned\\_by\\_Public\\_Health\\_England\\_FINAL.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/733022/E-cigarettes_an_evidence_update_A_report_commissioned_by_Public_Health_England_FINAL.pdf)

<sup>8</sup> [E-cigarettes are less harmful than smoking](#). Nutt DJ, Phillips LD, Balfour D, Curran HV, Dockrell M, Foulds J, Fagerstrom K, Letlape K, Polosa R, Ramsey J, Sweanor D. Lancet. 2016 Mar 19;387(10024):1160-2. doi: 10.1016/S0140-6736(15)00253-6.PMID: 27025332

<sup>9</sup> Eurobarometer 506, page 14

<sup>10</sup> [Je choisis la vapoteuse \(tabac-info-service.fr\)](http://Je.choisis.la.vapoteuse(tabac-info-service.fr))

Sincerely

Dr Karl Fagerström

Dr Francis Crawley

Dr Eva Kralikova

Dr Karl Erik Lund

Dr Bernd Michael Rode

Dr Ernest Groman

Dr Jacques LeHouezec

Dr Michael Kunze

Dr Anders Milton

Dr Heino Stöver

Dr Fabio Beatrice

Dr Delon Human

Dr Fabio Lugoboni

Dr Riccardo Polosa

Dr Stefan Willers

## About the authors of the letter:

- **Dr Karl Fagerström** was born in Sweden in 1946. He studied at the University of Uppsala and graduated as a licensed clinical psychologist 1975. At that time he started a smoking cessation clinic and invented the Fagerstrom Test for Cigarette Dependence. In 1981 he got his Ph.D. on a dissertation about nicotine dependence and smoking cessation. In the end of the seventies and early eighties he served as the editor – in – chief for the Scandinavian Journal for Behaviour Therapy. From 1983 through 1997 he worked for Pharmacia & Upjohn as Director of Scientific Information for Nicotine Replacement Products. He has worked with the nicotine gum Nicorette since 1975 and has been contributing to NRT developments such as patch, spray, pouch and inhaler. Ever since 1975 to 2010 he has been working clinically part-time. From 1997 to 2008 he worked with his private research clinic where he studied various drugs intended for treating nicotine dependence. Currently he works with his own private consultancy (Fagerström Consulting). He is a founding member of the Society for Research on Nicotine and Tobacco and currently a Deputy Editor of the Nicotine & Tobacco Research. He started the European SRNT affiliate in 1999 of which he was been the president up to 2003. His main research contributions have been in the fields of Behaviour Medicine, Tobacco and Nicotine with 170 peer reviewed publications of which he is the first author of 100. The current main interests are on understanding the positive effects of nicotine and reducing harm and exposure to tobacco toxins among all those who cannot give up smoking. He was awarded the WHO medal 1999 for outstanding work in tobacco control. Recently he was announced to be the recipient of the 2013 Award on Clinical Science from the Society for Research on Tobacco and Nicotine.
- **Dr Ernest Groman** is from Vienna in Austria and born 1969. He completed his medical school studies 1997. Already at this time was Dr Groman very interested in nicotine dependence and smoking cessation and he has since devoted the majority of his time to offering smoking cessation treatments at many different parts of the Austria society. He is the scientific director of the Nicotine Institute in Vienna. Dr Groman is a firm advocate for harm reduction in the field of nicotine addiction. He has written a book on smoking cessation and published numerous articles. He is an advisor to the Austrian Dept of Health and has been the Austrian delegate at WHO Framework Convention for Tobacco Control meetings. His qualification Associate Professor also includes the first “Habilitation” in the German region with the topic “Tobacco, Dependence & Public Health” (2001) at the University of Vienna.
- **Dr Fabio Beatrice** is Chief Emeritus of Otolaryngology and founder of the anti-smoking centre of the San Giovanni Bosco Hospital in Turin, Italy. He is the author of over 250 scientific publications including 57 on Pub Med and an author of scientific popularization books in the field of tobacco. He is also the Past President of the Italian Society of Tabaccology.
- **Dr Francis P. Crawley** is the Executive Director of the Good Clinical Practice Alliance – Europe in Brussels, Belgium. He is the co-founder and a Steering Committee member of the Strategic Initiative for Developing Capacity in Ethical Review. He is a philosopher specialized in ethical, legal, and regulatory issues in health research, teaching at several

European, Asian, and Middle East universities. He is the past Secretary General, Ethics Officer, and Chairman of the Ethics Working Party at the European Forum for Good Clinical Practice. He has acted as an author or expert for the leading international and European research ethics and GCP guidelines, as well as for several guidelines in Asia, Africa, the Americas, and Europe. Amongst other things, he is the committee chairman of the WHO guidelines on ethics committees and data monitoring committees; and was a member of the Scientific Advisory Committee for the World Health Organization's International Clinical Trials Registry Platform (ICTRP). He also served for four years on the UNAIDS Ethical Review Committee.

- **Dr Jacques Le Houezec**, trained as a neuroscientist in Paris, France, has been working on nicotine and smoking cessation for more than 35 years. He is a Consultant in Public Health & Tobacco dependence, and a smoking cessation specialist. He is also Manager of Amzer Glas - CIMVAPE, a training and certification organisation, based in Rennes, France.
- **Dr Delon Human** M.B.Ch.B., M.Prax.Med, MFGP, DCH, MBA is a French citizen and physician qualified in family medicine and child health, with an MBA from the Edinburgh Business School. He is a published author and health care consultant specializing in global health strategy, harm reduction and health communication. He has been active in tobacco control for decades, including advocacy for taxes on combustible tobacco to drive down consumer demand. He has acted as adviser to WHO Director-Generals and UN Secretary-General Ban Ki Moon. Formerly, he was Secretary General of the World Medical Association (WMA), the global representative body for physicians and thereafter Secretary General of the International Food and Beverage Alliance (IFBA). He is a fellow of the Russian and Romanian Academies of Medical Sciences. Delon has been involved in harm reduction in tobacco and nicotine, alcohol and drugs for the last 25 years. In clinical medicine, his work focused on tobacco cessation programs, while in medical politics, the development of the FCTC. He was Chair of the coordinating committee for NGOs in preparation of World No Tobacco Day 1999. He authored the book "Wise Nicotine".
- **Dr Eva Kralikova**, MD, is Professor and teacher at the First Faculty of Medicine, Charles University in Prague, Czechia, and head of the Centre for Treatment of Tobacco Dependence at the 3rd Medical Department, First Faculty of Medicine, Charles University and the General University Hospital. She is involved in epidemiology, prevention and treatment of tobacco dependence for about 30 years both on the national and international level.
- **Dr Michael Kunze** was born in Vienna, Austria. He studied at Medical School, University of Vienna and was research assistant at the Institute of Hygiene, University of Vienna 1968. At 1972 he became Head, Department of Social Medicine, Institute of Hygiene, University of Vienna and full professor at the same institute 1983. He has 800 publications. He developed diagnostic and treatment procedures for tobacco dependence already in the late 1970s and has been involved with studies on price policies to control cigarette consumption and published the first report on smoking and health in Austria 1973. Prof Kunze has been a temporary advisor to WHO and chairman of the UICC-project "smoking cessation"

- **Dr Fabio Lugoboni, MD**, was Born in Verona, Italy, in 1957. He is Director of the Addiction Unit at the University Hospital, Verona, Italy and is Adjunct Professor, Psychiatry School, University of Verona. He works with hospitalization of addicted patients from psychoactive licit and illicit substances. His main research areas are Substance Use Disorders and comorbidities, safety, adherence and efficacy of hepatitis vaccines among drug users, Nicotine dependence and drug treatment, Benzodiazepines: epidemiology of abuse and treatment and compliance and adherence to drug treatments. He has 6 times won The National Award Federer (2011-2016) and the first prize Persona-Comunità 2017. He is the Scientific Referee of the Fondazione del Monte and of the Swiss National Science Foundation and is advisory member of the Italian Board on Opioid Induced Constipation. He has served as President of 20 national conventions, authored several books and more than 100 articles listed on PubMed.
- **Dr Karl E. Lund** is currently senior researcher at the Norwegian Institute of Public Health. He was Research Director at the Norwegian Institute for Alcohol and Drug Research for the period 2006-2018. Dr Lund has been involved in tobacco control work since the mid-1980s, working at the Norwegian Council on Tobacco or Health (Deputy Leader), the Norwegian Cancer Society (Director Department of Cancer Prevention), University of Oslo and The Norwegian Institute of Public Health. He received the Norwegian Medical Association's Award in preventive medicine in 2000. Dr Lund has been a member of several expert committees including WHO's International Agency for Cancer Research (IARC). He is Associate Editor in four scientific journals and chaired the organizing committee for the 19th European SRNT-conference. He has been an expert witness for the plaintiff in several tort liability lawsuits against the tobacco industry. Dr. Lund holds a Ph.D. in Sociology from 1996 and he was formally assessed with qualifications as Professor in 2009.
- **Dr Anders Milton**, B.Sc., M.D., Ph.D. was born in Sweden. He is the president of ERNA, a member of the government appointed Catastrophe Commission and a consultant within the health care sector. Dr. Milton is also on the board of publicly traded Q-Med AB and has been chairman of the Board of Vironova since 2008. Dr. Milton has a long history of elected as well as government appointed positions. He has previously been both CEO and Secretary General of the Swedish Medical Association, chairman of the Council of the World Medical Association, Chairman of the Swedish Red Cross and Chairman of the Swedish Confederation of Professional Associations (SACO), as well as Government appointed coordinator of psychiatric services in Sweden and government appointed chairman of a committee on HIV/AIDS.
- **Dr Riccardo Polosa** is the Director of the Institute for Internal Medicine and Clinical Immunology of the University of Catania, Italy. He is co-author of the recently published book "Analytical Assessment of e-cigarettes". He is also in charge of the University's Centre for Tobacco Research (CPCT) and is Honorary Professor of Medicine at University of Southampton, UK. An internationally recognized leader in the field of clinical bronchoprovocation (airway challenge studies), he has published more than 250

peer-reviewed articles and books, mainly on respiratory medicine, clinical immunology, and tobacco addiction. After many years of service as President of the Italian Anti-Smoking League (LIAF: Lega Italiana Anti Fumo), he now serves as its Chief Scientific Advisor. Affiliations and Expertise: Institute for Internal Medicine and Clinical Immunology and Centre for Tobacco Research (CPCT), University of Catania, Catania, Italy; Faculty of Medicine, University of Southampton, Southampton, UK.

- **Dr Bernd Michael Rode** is a professor in chemistry. He became professor of inorganic and theoretical chemistry at the University of Innsbruck, Austria, in 1979. In 2011 he retired from university and is today active as honorary president of ASEAN-European University Partnership Network (ASEA UNINET:>80 European and Asian Universities). He has published more than 500 papers in international research journals, including book contributions. His main research areas have been ab initio quantum mechanical simulations of liquids/solutions, electrolyte solution structure and dynamics and chemical evolution of peptides/proteins and origin of life. He is CoFounder of ASEA-UNINET, CEO of Vape Research Company, Austria, President of UNCSTD (United Nations Commission Science and Technology for Development), 2004-2005, Vice-President 2002-2004, 2006-2008 and Councillor, International Society for the Study of the Origin of Life, 2008-2011.
- **Dr Heino Stöver** is a social scientist, PhD and Professor of Social Scientific Addiction Research at the Frankfurt University, of Applied Sciences in Germany, Faculty of Health and Social Work. Since 1987 he has been director of the Archive and Documentation Centre for Drug Literature and Research at the University of Bremen. He is the president of the national umbrella organisation working on harm reduction for drug users, called akzept e.V. (Bundesverband für akzeptierende Drogenarbeit und humane Drogenpolitik. Since 2009 he has been the director of the "Institute of Addiction Research". Heino Stöver's main fields of research and project development expertise are health promotion for vulnerable and marginalised groups, drug services, prison health care and related health issues (especially HIV/AIDS, Hepatitis C, drug dependence, and gender issues), and the potential of e-cigarettes. His international research and consultancy expertise includes working as a consultant for the European Commission, United Nations Office on Drugs and Crime (UNODC), World Health Organization (WHO), European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), International Committee of the Red Cross (ICRC) and Open Society Institute (OSI) in various contexts. He has published several articles in peer reviewed international journals and books on preventing and treating infectious diseases adequately (HIV/AIDS, hepatitis, STIs, and TB), opioid substitution programmes (including the provision of heroin) in the community and in prisons, and general health care issues. He is cofounder of the International Journal of Prisoner Health.
- **Dr Stefan Willers**, MD, PhD is associate professor and consultant, since 1994, at Skåne University Hospital (SUS) Lund/ Malmö, Sweden. He is currently with the Department of Respiratory Medicine & Allergology. He has published more than 100 times; 30 original publications, 24 of them published in international journals, 20 original publications within the research on tobacco. Further, he is a consultant in smoking cessation for Region Skåne and responsible for the tobacco treatment program.

