

DIRECTORATE-GENERAL FOR INTERNAL POLICIES

POLICY DEPARTMENT
ECONOMIC AND SCIENTIFIC POLICY **A**

Economic and Monetary Affairs

Employment and Social Affairs

**Environment, Public Health
and Food Safety**

Industry, Research and Energy

Internal Market and Consumer Protection

**Workshop on
Electronic Cigarettes**

MEETING DOCUMENT



DIRECTORATE GENERAL FOR INTERNAL POLICIES
POLICY DEPARTMENT A: ECONOMIC AND SCIENTIFIC POLICY

WORKSHOP

Electronic Cigarettes

Brussels, 7 May 2013

MEETING DOCUMENT



ЕВРОПЕЙСКИ ПАРЛАМЕНТ PARLAMENTO EUROPEO EVROPSKÝ PARLAMENT EUROPA-PARLAMENTET
EUROPÄISCHES PARLAMENT EUROOPA PARLAMENT ΕΥΡΩΠΑΪΚΟ ΚΟΙΝΟΒΟΥΛΙΟ EUROPEAN PARLIAMENT
PARLEMENT EUROPÉEN PARLAIMINT NA HEORPA PARLAMENTO EUROPEO EIROPAS PARLAMENTS
EUROPOS PARLAMENTAS EURÓPAI PARLAMENT IL-PARLAMENT EWROPEW EUROPEES PARLEMENT
PARLAMENT EUROPEJSKI PARLAMENTO EUROPEU PARLAMENTUL EUROPEAN
EURÓPSKY PARLAMENT EVROPSKI PARLAMENT EUROOPAN PARLAMENTTI EUROPAPARLAMENTET

Organised by the Policy Department A-Economy & Science for the Committee on the Environment, Public Health and Food Safety (ENVI) and the ENVI Secretariat

Workshop on Electronic Cigarettes

**Tuesday, 7 May 2013 from 12.30 to 15.30
European Parliament, Room PHS 5B001, Brussels**

AGENDA

12.30 - 12.35

**Welcome and opening by Linda McAvan, MEP, ENVI Committee.
Rapporteur on Tobacco Products Directive**

12.35 - 12.40

**The current position of the European Commission
Mr Martin SEYCHELL, Deputy Director General, SANCO**

Part 1

Institutional Representation

12.40 - 12.55

**Latest evidence from the WHO on e-cigarettes
Mr. Roberto BERTOLINI, Chief Scientist and WHO Representative to the
European Union.**

12:55 - 13:10

Q&A

Part 2

Questions to the European Regulators on e-cigarettes

13.10 - 13.50 (40 min)

United Kingdom: new regulation of e-cigarettes

Mr. Jeremy MEAN, Access and Information for Medicines and Standards Group Manager, Vigilance and Risk Management of Medicines, London (UK).

Germany: new regulation of e-cigarettes

Dr. Kerstin STEPHAN. Drugs - Cosmetics; Drugs - Food; Biocides, Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) (DE)

Finland: new regulation of e-cigarettes

Dr. Kristiina PELLAS, Senior pharmaceutical inspector, Finnish Medicines Agency (FI).

Part 3

Scientific information: clinical and research findings

13.50 - 13.55

Electronic Nicotine Delivery Systems – a known unknown.

Prof. Francesco BLASI. President of the European Respiratory Society.

13.55 - 14.00

Cardiovascular effects of tobacco. Long-term effects.

Focus on e-cigarettes.

Dr. Charlotta PISINGER, Senior research fellow at Research Centre for Prevention and Health, Copenhagen, (DK).

14.00 - 14.05

Understanding nicotine addiction

Dr. Jean-Francois ETTER, Faculty of Medicine in the University of Geneva (CH).

14.05 - 14.30

Q&A

Part 4

The voice of consumer associations

14.30 - 14.35

"Interessengemeinschaft E-Dampfen" (IG-ED), German e-cigarettes users association (DE)

Mr. Hans Christian HOLY

14.35 - 15.25

General Discussion

15.25 - 15.30

Conclusions

15.30 Closing

SHORT BIOGRAPHIES OF EXPERTS

Mr Martin Seychell

A graduate in chemistry and pharmaceutical technology, Mr. Seychell specialized in Chemical analysis. He has held important positions on several government boards and commissions in Malta, including the Food Safety Commission and the Pesticides Board. Mr Seychell occupied the post of Head of Directorate at the Malta Standards Authority between 2001 and 2006. He has been responsible for the implementation of a number of EU directives in the areas of risk assessment, food safety, chemicals and cosmetic products legislation, and has actively participated in negotiations on major technical proposals such as the new chemicals legislation, REACH, and in screening processes in the areas of free movement of goods, environment and agriculture during the process leading to Malta's accession to the EU. He held the post of Director of Environment in Malta between 2006 and 2011. As Director, he was responsible for a broad range of functions arising from the Maltese Environment Protection Act. He was appointed Deputy Director General for Health and Consumers at the European Commission in March 2011.

Text

Dr Roberto Bertollini

Dr Roberto Bertollini, M.D., M.P.H. is the WHO Representative to the EU in Brussels and the Chief Scientist of the WHO Regional Office for Europe. Before this assignment, he was the coordinator of the Evidence and Policy for Environment and Health unit of the WHO Department of Public Health and Environment in Geneva (2007-2010), the Director of the WHO EURO Special Programme on Health and Environment in Copenhagen, Rome and Bonn (2004-2007), the Director of the Division for Technical Support "Health Determinants" at the WHO Regional Office for Europe based in Copenhagen (2000-2004) and the Director of the Rome Division of the WHO European Centre for Environment and Health (1993-2004). Before joining the WHO he had worked at the Epidemiology Unit of the Lazio Region of Italy.

Dr Bertollini holds a degree in medicines and a postgraduate degree in paediatrics, as well as a Master in Public Health. During his career he has been involved in the development of the public health agenda at both European and global levels.

Dr Bertollini is highly interested in topics that concern the effects of social, environmental and behavioural determinants to human health. He is the author of many public health related scientific books and articles.

Mr Jeremy Mean

Jeremy Mean is the Access and Information for Medicines and Standards Group Manager in the Vigilance and Risk Management of Medicines Division (VRMM) of the UK's Medicines and Healthcare Products Regulatory Agency. Jeremy is a career civil servant, having joined the service in 1984, and has worked in a succession of policy and management posts in the UK's Department of Health. Within the MHRA, Jeremy's current role includes operational policy and delivery through teams covering advertising standards, patient information, reclassification of legal status and outreach and education functions. Jeremy also leads project groups on a range of high profile issues, covering both UK and EU policy.

Dr Kerstin Stephan

Kerstin Stephan (1969):

1988-1993 Studies of chemistry and pharmacy

1994 Pharmacist License

1996-1999 Scientific research at the Institute for pharmaceutical Chemistry University Bonn and at the Institute for Pharmacology, University Cologne

1999 Doctorate (Dr.rer.nat)

1996-1999 Post educational qualification: specialist license: "Pharmacist for Drug information"

2001-2005 Assessor validation unit, Federal Institute for Drugs and Medical Devices

2006 - today Head of subunit "General inquiries and Demarcation" of the validation unit

Since 2009 Member of the Borderline and Classification MDEG of the European Commission

Since 2010 Member of the Medical Device – Medicinal Product ad hoc Working group on borderline cases of the European Commission

Dr Kristiina Pellas

Kristiina Pellas works since 2007 as a Senior Pharmaceutical Inspector for the Finnish Medicines Agency - FIMEA (www.fimea.fi) in Helsinki (Finland) with a focus on borderline classification issues and regulation of advertising of medicines. She has wide experience in classification decisions at national and Nordic level.

She received her Master of Science degree in Pharmacy (Drug Information) from the University of Kuopio in Finland in 1988. During 1990 - 2007 she worked for the Pharmaceutical Information Centre in Helsinki as a publication pharmacist and education manager. She has produced training courses and e-learning programs related to regulation issues in RA, GMP and GCP and promotion of medicines for pharmaceutical companies in Finland.

Electronic cigarettes and nicotine liquids have been an on-going topic in borderline classification procedures since 2008 in Finland. During these years FIMEA has made statements for the customs and other authorities in classifying nicotine liquids for e-cigarettes as medicinal according to the effect and pharmacological mechanism of action of nicotine in human body.

Prof. Francesco Blasi

Francesco Blasi, MD, is Professor of Respiratory Medicine, Vice-chairman Department of Pathophysiology and Transplantation University of Milan, Director of Respiratory Diseases Unit IRCCS Fondazione Cà Granda Ospedale Maggiore Milan, Italy.

Professor Blasi is President of European Respiratory Society (ERS) 2012-13. Professor Blasi has published more than 180 papers in international journals. He is member of the Editorial Boards of Pulmonary Pharmacology and Therapeutics (Associate Editor), Respiratory Research (Associate Editor), Clinical Respiratory Journal (Associate Editor), Therapeutic Advances in Respiratory Disease (Associate Editor), American Journal Respiratory and Critical Care Medicine (member of the Editorial Board). His research interests include the effects of atypical bacteria infection on cellular immunity in chronic bronchitis, and the role of atypicals and viral infection in asthma onset. He is also interested in the role of antibiotics in the treatment of COPD exacerbations and asthma. He is also actively working on pneumonia and tuberculosis research trials. Professor Blasi has served on ERS-ESCMID guidelines on LRTIs and is member of the European Respiratory Society, The American Thoracic Society and the Italian Respiratory Medicine Society (SImeR).

Dr Charlotta Pisinger

Charlotta Pisinger:

January 1988 Medical doctor, University of Copenhagen

October 2004 Ph.D., University of Copenhagen

June 2007 Master of Public Health, University of Copenhagen

September 2009 Associate professor at University of Copenhagen, Faculty of Medical Science, MPH (Master of Public Health).

February 2011 Approved as qualified for Professorship

Scientific Theses:

Ph.D. thesis: "Smoking cessation and smoking reduction in a general population. The Inter99 study". Defended Oct. 2004

MPH (Master of Public Health) thesis, "High risk strategy in smoking cessation is on a population based level. The Inter99 study". Defended June 2007

Total number of published peer-reviewed papers: 53 (18 as first author, 5 as last author)

Position of trust (selected):

Vice-president of Danish Society on Epidemiology

President of Danish Society on Tobacco Research (2005-2010)

Member of the steering committee of the Inter99 study

Member of the Health Committee, Medical District Association, Copenhagen County (2005-2007)

Dr Jean-Francois Etter

Jean-François Etter is professor of public health at the Faculty of Medicine of the University of Geneva in Switzerland. He obtained a PhD in political science and a master degree in public health from the University of Geneva. He is an internationally recognized expert in the study of tobacco dependence and the development and evaluation of interventions to prevent smoking. He is a pioneer in research on electronic cigarettes, a new nicotine delivery system. He is also a pioneer of individualized interventions and automated support for behaviour change using the Internet and applications on mobile devices. He was one of the first to explore some new indications for nicotine replacement therapy, including the reduction of tobacco use among smokers who did not want to stop.

Mr Hans Christian Holy

Hans Christian Holy (1981)

Education / Profession:

Matriculation standart in 2002

Apprenticeship

Forwarding Agent

14 years smoker, 1 year e-vaper

PRESENTATIONS

Presentation by Prof. Francesco Blasi



**European Parliament – (E-Cigarettes) Workshop
7th May 2013:**

**Electronic Nicotine Delivery Systems
– a known unknown**

Prof. Francesco Blasi
President of the European Respiratory
Society

european respiratory society *every breath counts*

**THE EUROPEAN RESPIRATORY
SOCIETY**





“There are **known knowns** - things we know that we know.

There are **known unknowns** - things that we know we don't know.

But there are also **unknown unknowns** - things we don't know we don't know.”

Donald Rumsfeld – former US Defence Secretary

european respiratory society **every breath counts**

WHAT WE KNOW

- ENDS - Electronic Nicotine Delivery Systems are designed to deliver nicotine to respiratory system.
- Multiple brands are marketed under a variety of terms such as “electronic cigarettes” or “e-cigs”
- Significant increase in EU distribution & sales of these products since arrival on market around 2006-7.
- ENDS typically consist of propylene glycol, nicotine & flavourings.

WHAT WE DO NOT YET KNOW

- Effects on the lung?
- Extent of nicotine uptake?
- Emissions & health impacts of the vaporisation compounds?
- Other potentially harmful chemicals?
- Overall - health benefits and/or risks or long-term effects?

DUTY OF CARE

- Where scientific evidence is insufficient, inconclusive or uncertain;
- Leading to reasonable grounds for concern;
- Where there are potentially dangerous effects on humans;
- The precautionary principle should apply in order to manage risks.

SOLUTIONS

We need independent EU supported research:

- Independent Clinical trials
- Behavioural & psychological studies
- Post-marketing studies at individual & population levels across Europe
- Any regulation must be science based and in line with UN Treaty – WHO Framework Convention on Tobacco Control



european respiratory society every breath counts

ersnet.org

Presentation by Dr Charlotta Pisinger



Electronic cigarettes Let's not repeat the errors of the past

Charlotta Pisinger

PhD MPH Ass Prof Consultant

E-mail charlotta.pisinger@regionh.dk

Research Center for Prevention and Health

Capital Region of Denmark



Conflict of interest

- I have nothing to declare

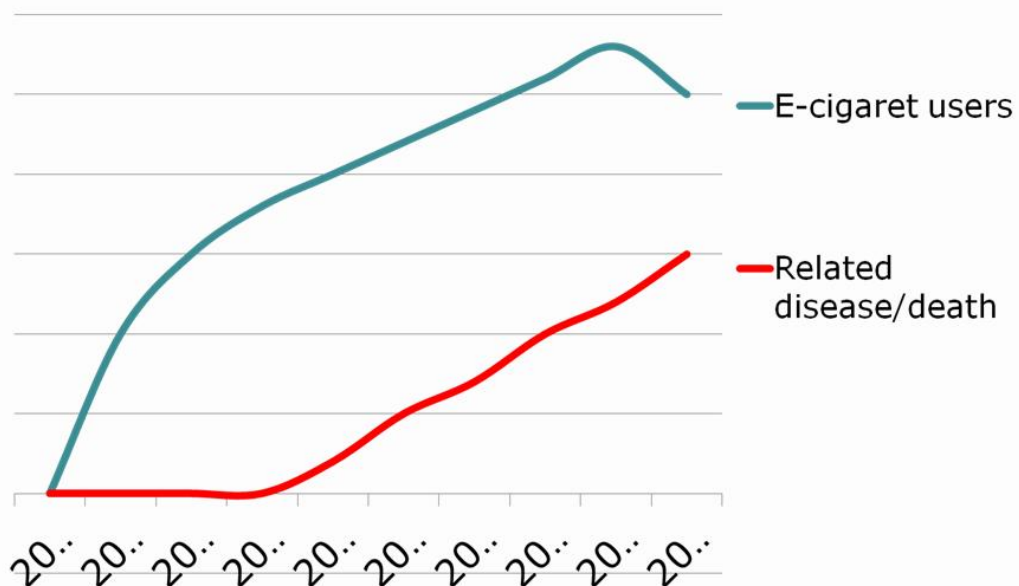


Our knowledge of e-cigarettes = as of smoking 100 years ago

- People have used e-cigarettes for a few years
- Users are often in their 30s and 40s
- At this age, incidence of cardiac disease is very low



Time delay of health consequences



Fortune telling

We need hundreds of thousands of users and many more years of use in order to see any *long-term effects* of e-cigarette on cardiovascular health



Safety concerns

- Components found: nicotine, toxins and carcinogens
- Mostly only 'traces' of toxins but the inhaled aerosol undergoes changes in the human lung



Acute effects on the heart Small experimental studies

Some studies: significantly increased

- Plasma nicotine
- Heart rate
- Blood pressure



Other studies: no significant effect

- Plasma nicotine
- Heart rate
- Blood count markers

Misleading information on product ingredients

- This probably reflects that both the dosage of nicotine and the content of other chemicals vary markedly across the products
- Poor consistency between actual nicotine content and the amount labeled
- Labels 'without nicotine' contains nicotine



US Food and Drug Administration

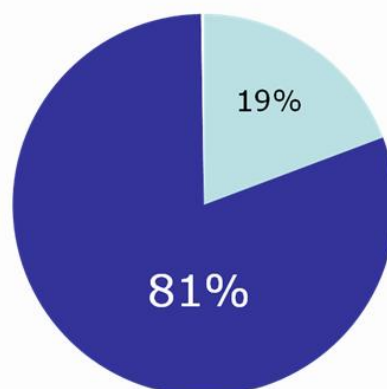
- Increasing number of adverse events reported
- Many with causal relationship
- Reported cardiovascular events:
 - Rapid heartbeat
 - Chest pain
 - Hypotension
 - Hospitalisation for congestive heart failure...



Analysis of original posts from three online e-cigarettes forums

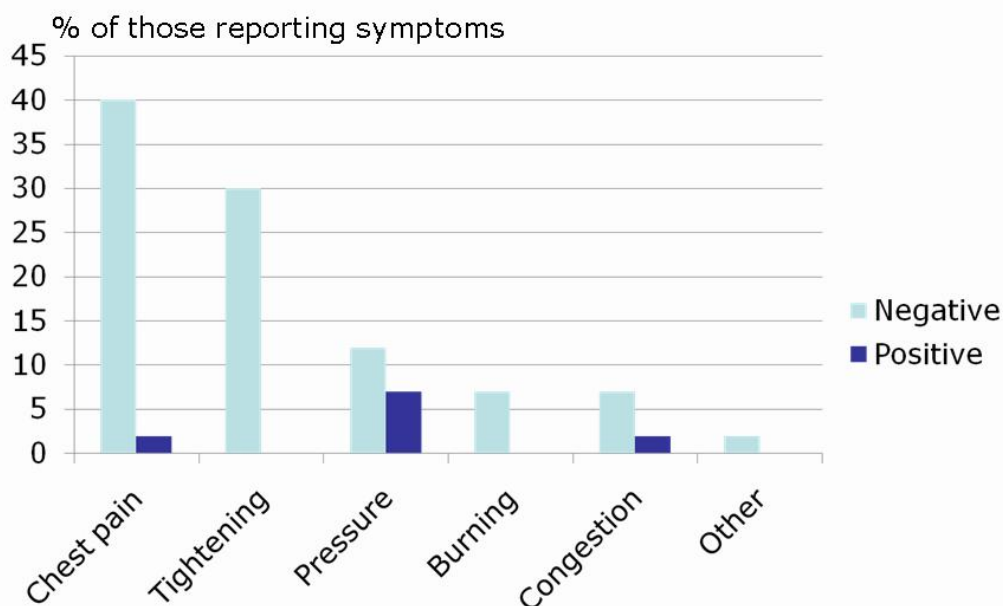
405 self-reported symptoms

■ Positive ■ Negative



My Hua, Health-Related Effects Reported by Electronic Cigarette Users in Online Forums. J Med Internet Res 2013;15(4):e59

Self-reported symptoms from the chest

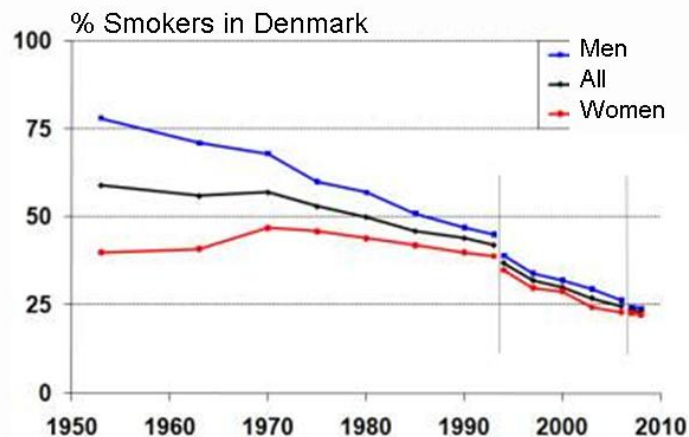


The 'light' catastrophe



Less toxic than cigarettes

- "Harm reduction" - is that good enough?
- We want smokers to quit
- It takes time but it is possible

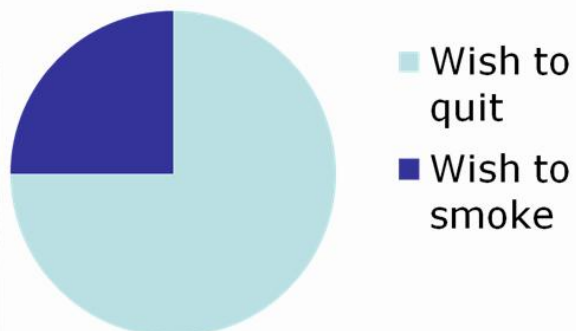


Three out of four smokers wish to quit

- Cardiovascular disease: the N°1 killer in Europe, the death of 1.9 million EU citizens yearly
- Smoking causes 28% of CVD deaths



Surveys



Smoking cessation efficacy

- A nationally representative cross-sectional survey of almost 2000 current or recently former adult smokers
- 4 out of ten had tried an alternative tobacco product, most frequently e-cigarettes
- **Use was not associated with successful quit attempts**
- Alternative tobacco products are attractive to smokers who want to quit smoking, but we need evidence that e-cigarettes promote cessation

Popova L. Am J Public Health. 2013 May;103(5):923-30.



Kids are fast learners – they can not see the difference



European Society of Cardiology Proposal

- Let's not repeat the errors of the past (cigarettes, light cigarettes)
- We need scientific evidence on safety and efficacy
- E-cigarettes must be tightly regulated by national/EU authorities as both a tobacco and a medical product
- If shown to be efficacious and safe, e-cigarettes *could* be an alternative smoking cessation aid to standard nicotine products



Presentation by Dr Jean-François Etter

Addictiveness of e-cigarettes

- Jean-François ETTER, PhD
Professor of public health
Faculty of Medicine
University of Geneva, Switzerland
- EU Parliament
- 7 May 2013

Addiction

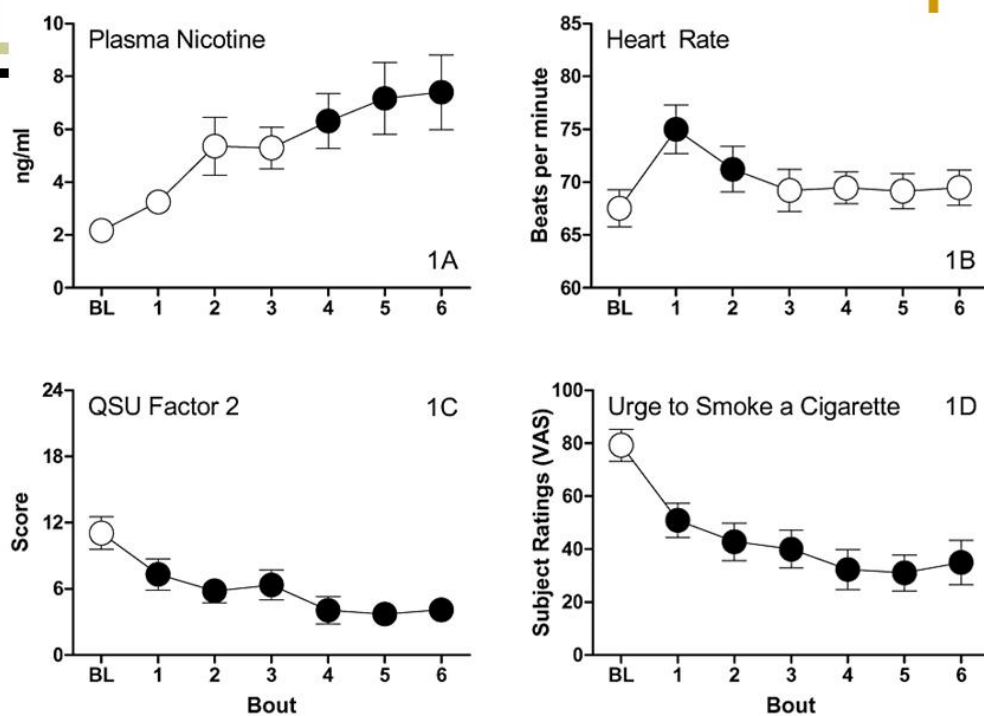
- Definition:
- Compulsive use in spite of adverse consequences for the user's health, family and social life
- The « adverse consequences » element is lacking for e-cigs

Do e-cigs deliver a satisfactory amount of nicotine ?

N	30
Daily e-cig users	97%
Used tobacco or NRT in past 48h	0
Puffs / day on e-cigs (median)	200
Cotinine in saliva, median 25 th / 75 th percentiles	322 ng/ml 138 / 546 ng/ml
<i>In the literature: in ex-smokers who use NRT:</i>	<i>100-250 ng/ml</i>

Etter JF, Bullen C. *Eur Respir J.* 2011 Nov.

Vansickel et al, *Addiction*, 2012;107:1493



Addictiveness

- Surveys of vapers:
 - Vapers are former and current smoker
 - 97% to 100% of vapers use nicotine-containing e-cigarettes
- Thus, e-cigs are nicotine-delivery devices
- **Addictiveness depends on the speed of delivery to the blood**
- Nicotine is highly addictive when smoked
- Some users are addicted to the nicotine gum
- Nicotine in patches are not addictive
- Speed of delivery for e-cigs: quicker than for nicotine gum or inhaler, but slower than for cigarettes

Are e-cigarettes addictive ?

- This is not yet documented, but it is possible
- Some former smokers who were already addicted to nicotine probably use e-cigarettes compulsively
- Surveys suggest that addiction to e-cigarettes is weaker than addiction to tobacco (but this needs confirmation)
- Compulsive use of e-cigarettes can be treated
 - with nicotine patches, which are not addictive
 - with varenicline
 - and counseling by a clinician

Is it a public health problem ?

- Adverse consequences of long-term vaping are not yet documented
- But long-term vaping is much safer than smoking
- E-cigs help people quit smoking and avoid relapse
- Compulsive use of e-cigarettes can be treated, probably more easily than addiction to tobacco
- Comparison with nicotine gums:
 - 1% of smokers who quit smoking with nicotine gums remain addicted to these gums, but...
 - this is not a public health problem
 - nicotine gums are sold without a medical prescription

Gateway to smoking in young non-smokers ?

- Argument used by opponents, but this is not supported by data
- Surveys show that some adolescents use e-cigs, but addiction to e-cigs in adolescents has never been documented
- Fruit flavored nicotine gums are not a gateway to smoking in adolescent non-smokers
- Need for research on use of e-cigs by adolescent non-smokers

Are e-cigs used to inhale illicit drugs ?

- E-liquids with artificial cannabis flavor are available online
- Some e-cigs are advertised for use with cannabis leaves
- Survey: very few vapers admit to using e-cigs to inhale cannabis
- Heroin or cocaine? Not documented

Perspectives

- Research is urgent
- Safety ?
- Efficacy ?
- Addictiveness ?
- Use by non-smokers ?

Presentation by Mr Hans Christian Holy

E-Cigarette Workshop of the European Parliament, Brussels, May 7, 2013



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Knowing one Teddy Bear is knowing all Teddy Bears	10

26.04.2013

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1

The Miracle Drug that cures the Addiction it's suspected to cause



- E-Cigarettes are just an **alternative** to the tobacco cigarette.
- We are **not planning to stop** anything and **do not plan to change** our behavior.
- E-cigarettes **cannot be a medicinal product**. As by definition a medicinal product has the goal to cure, the e-cigarette is **not curing anything**, but rather **replacing** a proved harmful addiction with a far less dangerous enjoyment.
- Imagine to replace **coffee** with **tea** in case you have a weak stomach.

*There are already many studies and investigations concerning the e-cigarette. Unfortunately, they are mostly ignored or interpreted negative – even if they prove that e-cigarettes are much safer than tobacco cigarettes. **By purpose?***

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2

The Unsafe Haven



- Where is **the prove** that an e-cigarette respectively the e-liquids are **safer if we buy them in the pharmacy or as medicinal product**? Really, anyone who can please tell us.
- Reality is in big contrast to this thoughtless suggestion: a pharmaceutical product **does not need any dangerous substance markings**. Did you really think about this?
- "It's medicine and I bought it in the pharmacy, so it must be safe and I do not need to be cautious." **Is this really better?**

But anyway, the e-cigarette cannot be a pharmaceutical product as stated earlier. It is not for withdrawal and does not cure anything.

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3

Nicotine Guessworks



- There is not any evidence for the addictiveness of **nicotine standing alone**.
- On the other hand **there are studies (also from EU-institutes)** which nourish the perception that the **addictiveness of nicotine alone is insignificant**
- **Where is the evidence** that nicotine alone is the addiction-critical substance?

*Again, repeating and repeating non-proven arguments will not make them true. Is this done **by purpose**?*

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4

The Horror in small Bottles



- Nicotine is **safe in the usual concentrations**. There is also enough tolerance by far for not completely perfect devices (they will never be, may it be in a pharmacy or wherever).
- Eating tobacco is as dangerous as drinking e-liquid. Or eating **grated nutmegs**. Or drinking **toilet cleaner** (in nice colourful designed bottles, perfectly suitable for children).
- Harmful substances are **already regulated** within the EU.

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5

The Fairy Tale of Minors and Adolescents



- We see **no proofs or even indications** for the often repeated argument that minors start using nicotine with e-cigarettes.
- There are **often repeated rumours** telling 9 percent of Hungarian minors had contact to e-cigarettes in any way. We saw **no evidence** and we do not believe this until there is any clear evidence.
- We use E-Cigarettes **since years** and do not know any minor or adolescent who started using nicotine with an e-cigarette.
- A big majority have been **smoking tobacco for a long time** and are definitely no minors.
- E-cigarettes are **not "cool"** at all, expensive @ start, and annoy with a rather intricate handling.

*Why are unproved statements repeated so often? **By purpose?** Repeating does not make a lie more true.*

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6

Legal Impossibilities



- E-Cigarettes and E-Liquids **must not be regulated in the Tobacco Products Directive as they contain no tobacco at all**. The pure nicotine can be synthesised as well and it will then be exactly the same substance. Coca Cola is no Coffee.
- It is **absolutely illegal** to force a product which is proven to be so much less harmful into stricter regulations than the tobacco cigarette which is available almost everywhere.
- The European Citizen has the right for his own **self-responsibility**. How dare you taking this basic right away from the vapers? **We harm no others!**

*Everyone including the Commission knows that the Directive will probably fail at court later with regard to e-cigarettes. But they ignore this. **By Purpose?***

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7

Fight 600,000 EU Tobacco Smoking Deaths



- E-cigarettes could **help to reduce 600,000 deaths from tobacco smoke** each year in Europe.
- But **this will not work in the pharmacy resp. as a pharmaceutical product**. The planned regulation will kill the e-cigarette as it is known today. It will be like a nicotine gum – without any attractiveness for smokers to change over.
- They are a **means for enjoyment and stimulation** - very similar to a cup of coffee - and exist due to their freedom of availability, taste and the big **variety of flavours**. This will all be gone as a pharmaceutical product. **The consumers, the citizens of Europe do not want this to happen!**
- **We should not miss this great chance for harm reduction!**

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8

Vapour, Lies and Nitrosamines



- Despite of their highly sophisticated testing methods the FDA was not able to quantify the **nitrosamines** they found in a few e-liquids.
- To determine the content of nitrosamines they need 21-75 ppb. To just tell that nitrosamines are in you need about half of this.
- Further publication of the FDA results was forbidden by a US court
- Following that FDA-study, 1 ml of e-liquid contains:
 - up to **40 times less** than the pharmaceutical product nicotine gum
 - up to **15,000 times less than one cigarette**
 - Most e-liquids contain no nitrosamines at all

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9

Knowing one Teddy Bear is Knowing all Teddy Bears



Picture taken from RAPEX 2013-12
Ref. 31 A12/0408/13



- The RAPEX-tables contain all kinds of non-food goods. Are all **teddy bears** dangerous because **one** was in the Rapid Alert System? (Not much more to say here.)

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10

NOTES

DIRECTORATE-GENERAL FOR INTERNAL POLICIES

POLICY DEPARTMENT ECONOMIC AND SCIENTIFIC POLICY **A**

Role

Policy departments are research units that provide specialised advice to committees, inter-parliamentary delegations and other parliamentary bodies.

Policy Areas

- Economic and Monetary Affairs
- Employment and Social Affairs
- Environment, Public Health and Food Safety
- Industry, Research and Energy
- Internal Market and Consumer Protection

Documents

Visit the European Parliament website: <http://www.europarl.europa.eu/studies>

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