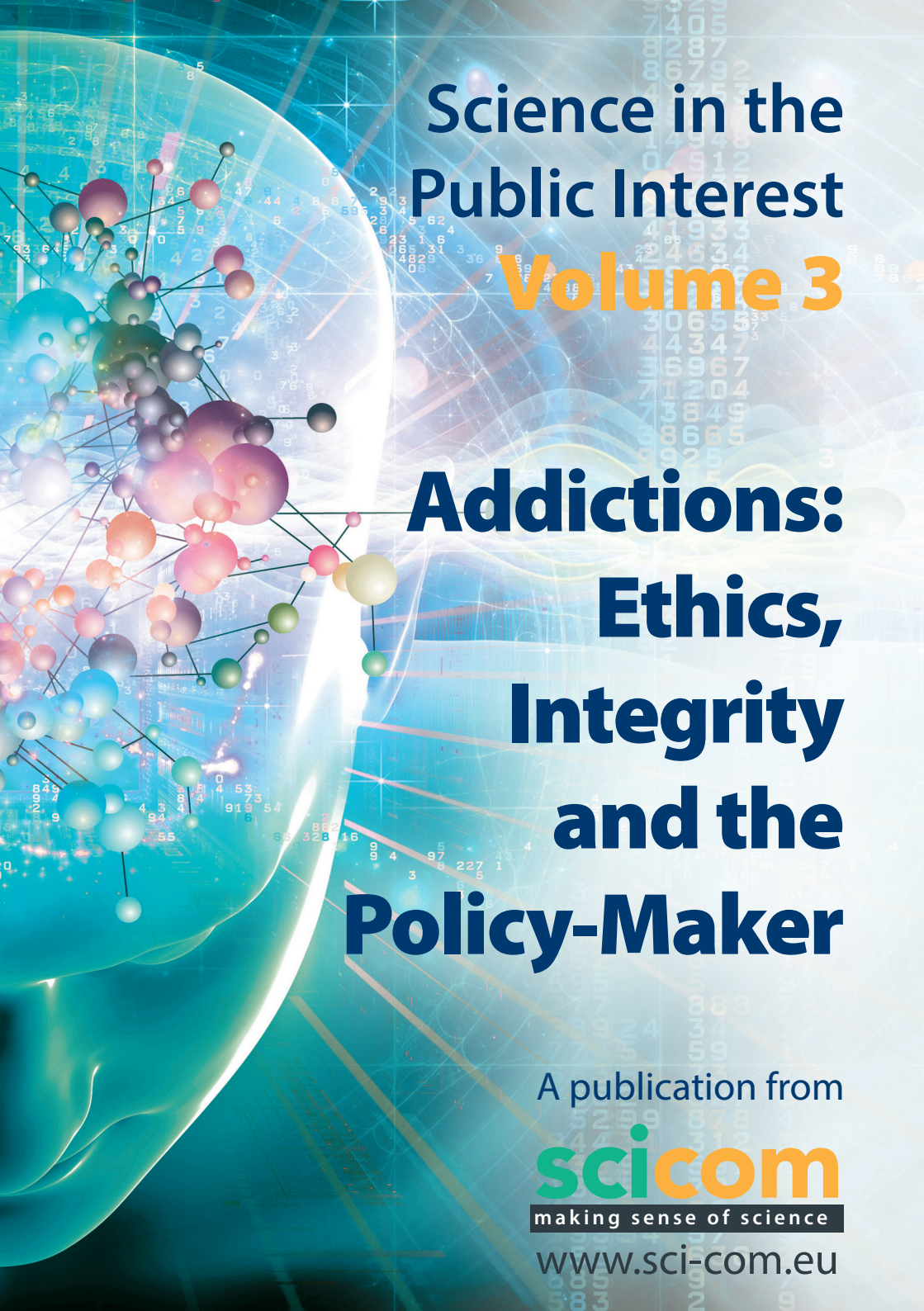

Science in the Public Interest

Volume 3

Addictions: Ethics, Integrity and the Policy-Maker

A publication from

scicom

making sense of science

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CONVENER'S PREFACE

THOUGHT-LEADER PERSPECTIVES

DRUGS

ALCOHOL

TOBACCO

STUCK IN THE MIDDLE

Disclaimer: *The opinions expressed herein reflect the personal views of the authors. They do not necessarily reflect the opinions of their organisations.*

Evidence-Based Policy Versus Policy-Biased Evidence:

The Challenge of Feeding Scientific Advice into Policy-Making

Addictions: Ethics, Integrity & the Policy-Maker

Key Findings and Recommendations
High-Level Consultation Event
Brussels June 2014

"Harm reduction science is arguably one of the best kept secrets in public health today. It has unquestionable potential to vastly improve how public, private and third party groups work together on preventable causes of disease and premature death linked to lifestyle."

Dr. Richard Horton Editor-in-Chief, *The Lancet*, Formerly First-President of the World Association of Medical Editors

Mr. Aidan Gilligan (IRL), Founder & CEO of **SciCom** – ***Making Sense of Science***; International Media Partner, **World Science Forum**; Elected Governing Board Member, **Euroscience**; Vice-Chair, International Media & Marketing Committee, **European City of Science** (ESOF 2016 Manchester); Planning Group Member, **The International Network on Science Advice to Governments.** ***Email: ag@sci-com.eu URL: www.sci-com.eu***

Convener's Message:

THE ETHICS OF POLICY INERTIA WHEN SCIENTIFIC FACTS ARE KNOWN: CONVENIENT BLIND SPOT OR INSTITUTIONALISED MANSLAUGHTER?

"Drugs have harmed many people but bad government policies have harmed many more". **KOFI ANNAN**

The purpose of this third in a series of five collections of free speech thoughts from some of the world's leading policy-makers, activists and producers of those lifestyle substances that risk killing us the most is simply to make the case for greater action on what the science of addiction is actually telling us. The aim is to separate scientific fact from fiction and help better explain the policy-making process, while all the time nudging those groups involved out of their silos, to build bridges, to change mind-sets and to further advance harm reduction science – basically to do the right thing.

Why? Because 1.5 billion people alive today will die prematurely and needlessly due to substance addictions like tobacco, alcohol and drugs. Let that sink in. One billion will die from smoking-related diseases; half a billion will die from drinking; and some 35 million will die from drug-related use *(excluding violent deaths linked to the drugs trade)*. In 2015 alone, 6 million people will die from smoking; 3.3 million people will die from drinking and 200,000 people will die from drug use *(Source: WHO)*.

At first sight, our eight contributors might appear a slightly odd bunch to bring together: the President of the European Group in Ethics advising European Commission President Juncker and the European Parliament; UN Secretary-General Ban-ki Moon's Health Envoy and the former Director of the Global Fund; the Chief Science Adviser to the Prime Minister of New Zealand and convenor of the International Network for Governmental Science Advice; the Chief Executive of leading advocacy group Action on Smoking & Health; the President of the world's largest Press Corps; the Chief Executive of an Association of Alcohol Producers; the Immediate Past-President of a leading Brain Research Foundation; and the Chief Medical Officer of an electronic cigarette producer.

This is done entirely on purpose, of course. *SciCom – Making Sense of Science* is an advocate for ***'science diplomacy'.*** If diplomacy is the art of getting people to engage with each other when they otherwise might not want to, then science diplomacy is about

encouraging stakeholders holding different opinions to meet, discuss and ideally agree some common ground. It is about establishing the most basic of starting-points: dialogue.

The task we set ourselves here is to explore the accessory role in these deaths – if any – of the broader policy-making environment, including national parliaments, the civil service, the legal profession etc. If the science is crystal clear, yet nothing meaningful is being done, or worse still if efforts to do so are being blocked and blind eyes are being turned, should we be holding decision-makers to account? Are they guilty, in the worst case scenario, of *'institutionalised'* manslaughter?

Over a period of five years from June 2012 until June 2016, ***SciCom – Making Sense of Science*** is partnering with leading authorities in public health governance to convene an annual **High-Level Consultation Event** looking at different angles of addiction. Each meeting is limited to approximately 40 scientists divided into pre- and onsite working groups, while a further 60 organisations are invited to a pre-event networking exchange. Dialogues and interactions take place over an extended period of time to reach group consensus on specific issues, while the flagship conference itself is coordinated by two highly esteemed individuals acting as Current and Incoming Chairs. This approach offers a high degree of continuity.

In June 2012, we partnered with CSAs **Prof. Anne Glover** (EU) and **Prof. Patrick Cunningham** (IRL) to explore the evolving science of ***Harm Reduction,*** establishing fifteen best-practice principles underpinning the five-year project *(see below)*. Five thought-leader pieces were also generated by participants. In June 2013, we partnered with **Dr. Wilson Compton** (US), Deputy Director, National Institute on Drug Abuse, National Institutes of Health (NIDA) to look at the evolving science of ***Addictions and their Brain-Reward Systems.*** Eight thought-leader pieces were generated by participants. In June 2014, we partnered with **Prof. Michel Kazatchkine** (FR), UN Special Envoy for HIV/Aids in the Office of Ban-ki Moon to look at the broader issues of ***Ethics, Integrity and the Policy-Maker.*** This compendium represents a follow-up of these ongoing, inter-twined discussions and offers thought-leader pieces, including two guest author perspectives. In June 2015, we will partner with **Prof. Julian Kinderlerer** (SA), President of the European Group of Ethics (EGE) to look at ***Addictions: Regulating Risk***.

The common thread uniting all these efforts from so many eminent groups is what one might call ***'science in the public interest'.*** The new thinking generated and new connections made regularly feed into proposals put forward to prominent scientific symposia open to the general public e.g. **The American Association for the Advancement of Science** (AAAS); **Euroscience Open Forum** (ESOF); **Word Science Forum** (WSF) etc.). Over time, this science diplomacy in action has built up into a unique repository of presentations, personal views and media comment (www.sci-com.eu).

WHY ASKING THE DIFFICULT QUESTIONS MATTERS

On paper, the reason for our out-of-control substance addictions is our own failing in

not heeding the warnings. In the developed world, our *'problems'* are well-documented and largely of our own making, often linked to exuberant life-style where we are lured to believe that only good things or stress relief can happen when we are drunk or high. As a corollary to these health warnings, we are told that thanks to modern science, any child born today can expect to live to see one hundred. In his analysis of ***'the ethics of intervening in the lives of substance addicts'*** that follows *(page 14)* Prof. Kinderlerer explores why our society both professes intolerance for the use of *'drugs'* and provides the social setting to enable and make legitimate their use.

Professor Kinderlerer asks are we really individuals anymore? Already neuro-marketing firms claim to be able to manipulate *'buy buttons'* inside the brain and influence consumer behaviour. Game developers advertise programmes that can *'train the brain'* to overcome the hindrances of old age and mental illness. Nutrition companies sell mood-boosting beverages and stress-busting snack bars. And policy-makers are increasingly hungry for insights from neuroscience to devise 'nudges' for their citizens.

It all sounds quite futuristic and far-fetched. But when you read Dr. Baker and Dr. Bridgman's joint essay on ***'mapping the brain, unlocking the mind, tackling addiction'*** *(page 26)* it is clear that the *'brain age'* is upon us. Science is already tapping into brain mapping discoveries to directly manipulate its function, for example, by inventing a daily pill that reduces the cravings of alcohol addiction. We can now literally *'see'* which smokers or heroin users are actually addicted. This form of direct chemical intervention is gaining ground. It raises **serious ethical questions about the responsibilities of individuals to look after themselves and those of States to look after their citizens.** My own belief is that it all boils down to where you stand on the notion that drinking, and indeed other addictions, is an unqualified right without any associated sense of societal responsibility.

Treatments aside, harm reduction and brain science are potential game-changers for those industries supplying the addictive substances in the first place. As Dr Bridgman suggests, the invention of the ecigarette is potentially the greatest disruptive technology — and potential public health opportunity — of our time.

Paul Skehan's piece on ***'alcohol: why evidence-based policies are often the exception rather than the rule',*** *(page 40)* examines why mixed public messages founded on unproven science are so dangerous. Whereas a bullet or plane crash kills in a sudden act and captures everyone's attention, it is pretty hard to identify which pack of cigarettes or which glass of wine actually might kill you, so regulation of responsibility is more complex. He proposes five underlying principles for *'good'* research *(relevance; neutrality & objectivity; fairness & transparency; robustness; & engagement)*, while calling for a more even-handed approach, especially by the European Institutions, to the acceptance of industrial science, at least on a par with NGO contributions.

Many readers will argue that as an alcohol salesman *"well, he would say that wouldn't he?"* But that is too simplistic an approach. The fact remains that industry is the largest investor in science and has every right to have its voice heard. We would be fools not to listen. Their success is both economical and societal. Most might claim not to like *'big pharma',* for instance, but few think of that when getting their medicine, having an operation or benefiting from

advances in anaesthesiology or the simple comforts of a modern ambulance.

NGOs and interest groups similarly are a crucial cog in the policy-making cycle. They must be transparent and accountable but, above all, take responsibility for the information they disseminate to suit their purpose. At this year's **Consultation Event** we heard a lot about some pretty questionable tactics from BINGOs *(Business Interest NGOs)* and DINGOs *(Direct Government Interest NGOs)*. When interest groups clearly get it right, both the scientific and policy-making community should give them the credit they deserve. When they get it wrong, they should learn to hold their hands up and contribute to dismantling the public myths about science they have helped create. Deborah Arnott, Chief Executive of Action on Smoking & Health's fascinating insight into the world of tobacco control raises ethical questions about the conduct of senior global health officials who toe the official scientific line while undermining it in equal measure.

ADDICTION: OUR GREATEST EXPORT

At the **World Science Forum** held in Rio in 2014, several G77 delegates expressed concern that the *'West'* is readily pushed as a lifestyle model that the *'East'* or *'South'* should aspire to *'develop'* to. One South African health expert commented that just as 15th century explorers brought the common cold to the shores of Rio killing millions of indigenous peoples, today the West's lifestyle vices are readily being *'exported'.*

Of course, it is more complicated than that, but we do know full well the harmful impacts of the substance exposure and addiction we are *'peddling'* to the poorer citizens of our planet. Just visit a trendy nightclub in Beijing or Bangalore where savvy alcohol marketing links incessant drinking games with seemingly innocuous board-game gambling. There is known to be a link between advertising and people's alcohol consumption, particularly those under the age of eighteen. Some countries – but very few – have introduced a complete ban on alcohol advertising *(Norway)* or a ban on TV advertising with other controls *(France)* to tackle this. Whereas a big stick has been taken to tobacco advertising pretty much everywhere in the *'West'* with the support of the *WHO's Tobacco Products Directive*, why is it that regulators adopt a soft-touch approach when it comes to alcohol? What are the vested interests there? Surely an Alcohol Products Directive is on the cards and if not, why not? This is certainly an issue to tackle in 2015 when we look at regulating addictions.

The whole image of a country and of a people can now be summed up in a bottle of beer like Carlsberg for Denmark or Guinness for Ireland. Is this harmless? Isn't it OK to say that alcohol kills, and increasingly so? **How have we arrived in a place where you have to justify why you smoke and why you don't drink?** As we fight Ebola and worry about bird flu and weather-driven catastrophes etc. it seems startling how nonchalant we have become about the substance addictions in practically every home.

This does not mean that everybody involved in providing scientific advice for policy-making is standing idly by and turning a blind eye. Let's be more optimistic. The race for ground-breaking brain research, in particular, is helping unlock the very secrets of our personalities, causing a revolution in how we might address addiction and frame public policy. A good example is a new pill readily prescribed by UK doctors to help kill cravings

in the brain for moderate drinkers at risk of sliding into dependency. Similarly, some would argue that not since the Internet has society seen a comparative disruptive technology with the capacity to so fundamentally impact (save) lives as the electronic cigarette. Hundreds of versions have sprung up, specialised shops cannot be built fast enough and Wells Fargo (2013) predicts that sales will outstrip classical cigarettes by 2021.

70% of smokers want to quit. More than 50% have tried ecigs with 33% of these continuing to use them. And 33% of those who continue actually give up nicotine altogether. This is surely wonderful. Yet, are e-cigs *'safe'* or simply 'safer'? If the former, shouldn't all harm reduction advocates welcome them? Or does their nicotine and flavorings-laced vapor risk developing cancer much in the same way that tobacco smoke does? Are they child-proof enough? Are they a gateway to smoking for teenagers? Should we freeze advertising until we know more? And what concerns should we have about the billions of discarded cartridges and lithium batteries?

What is clear from Deborah Arnott's insider's view is that, from a global perspective, regulation is chaotic. Some of the blame for this must surely lie with the many pseudo-scientific groups aiming not only to influence, but to confuse policy-makers and ultimately make decisions harder for them to take. Intentionally or unintentionally, they thrive on muddying the scientific waters. It all boils down to **whose science can you really believe?**

The greatest irony of all for me is that while discovering the complex workings of the brain we forget to factor in how people actually think! We could dedicate forests of paper to discussing the ins and outs of *'free choice'* and what science is now telling us about substance addictions and their brain reward systems. Public health officials and policy-makers are surely naïve if they believe that constant negative messages about the harm caused by drinking, smoking or taking illicit drugs is readily understood or will sink in. But as Dr. Mary Baker, Past President of the *European Brain Foundation* advocates, it would mark an important first step to reach agreement on whether **addiction is a brain disease or simply a weakness in the individual?**

When I put this question to Thomas Südhof, 2013 Nobel Prize in Medicine, best known for his work on synaptic transmission, at a public lecture in the European Parliament, he was unequivocal: **addiction is a brain disease.** He also went to great lengths to advocate that society needs to better understand the plight of the addicted person.

Ban-ki Moon's Health Envoy, M.D. Michel Kazatchkine's contribution titled ***'the splits emerging between repressive and health-focussed countries'*** *(page 33)* takes this logic even further. Doctor Kazatchkine gives a masterful snapshot of the gross inadequacies of current laws and policies. You do not need a PhD to see that a health-based approach to tackling addiction starts with the implementation and scaling up of harm reduction. Yet, the inconsistencies are manifest. In some countries, possession of a needle results in arrest. In others, citizens are obliged to call the police first, and perhaps an ambulance second, if they find a victim of overdose. Twelve countries are executing 1,000 people per year for drug offences. He warns that in particular, **the European Union, has lost the global public health leadership it once held.**

It struck many **High-Level Consultation Event** participants that the policy-maker

and the science of policy-making *per se* need closer scrutiny. Is the policy-maker a neutral broker between opposing factions, making a carefully weighted judgement? Or, if the science stacks up but the risks are perceived as too high to do the right thing *(loss of votes or job),* is he/she essentially guilty of *'institutionalised manslaughter'*?

In the first of our guest writer perspectives, New Zealand's Chief Science Adviser, Sir Peter Gluckman gives us his thoughts on ***'providing science advice to governments'*** *(page 20)* Many governments are now looking at creating the position of Chief Science Adviser and a new global CSA network is in its infancy. Sir Peter allows us to peek behind the curtains of how a mixed model of formal and informal science advice actually works in practice. Giving real-life examples from New Zealand of tackling teenage morbidity and recreational psychotropic drugs, he paints an honest picture about the use and limits of science advice and the realpolitik of policy formation in emotionally charged areas.

These ongoing discussions led to a new thought, the seed for our 2014 deliberations. We hear repeatedly about *'bad science'* or *'bad pharma'* but what about the roles and the responsibilities, ethical, political and indeed, legal, of the *'bad policy-maker'*? As Kofi Annan of the Global Commission on Drugs Policy and former UN Secretary-General puts it: "drugs have harmed many people but bad government policies have harmed many more".

WHY WE DO WHAT WE DO

We create a small splash in Brussels every year simply because nobody else does and it needs to be done. Having worked for the EU's scientific services for nearly ten years (2002 – 2012), I saw much good work being done and as a dedicated science diplomat, I am genuinely a big fan of the global scientific enterprise. Those were exciting times which I detailed in Compendium II. Looking back, however, my experience was that important legislation impacting the lives of everybody is often decided without the broader scientific inputs of those actually doing the science and *'in the know'.* The approach all-too-often is *'here's the policy we want, now find the science to support it'.* It really is an exclusive club with its own rules and rationale, as Paul Skehan critiques in his piece, while Ann Cahill's journalistic view ***'stuck in the middle'*** *(page 56)* adds further weight to the view that the end justifies the means when it comes to science and policy.

But we are not here as fault-finders. We aim to improve the status quo. To do that, you have to challenge it. When we began this journey in 2012 with an *'everybody's science is welcome'* strategy, we were lambasted, particularly by the European Commission's Health & Food Safety Directorate. But we will keep knocking on their door. EU Commissioner Vytenis Andriukaitis is a known believer in harm reduction. The WHO too has fluctuated from active support to walk-outs.

All told, some 250 groups have been involved. To their great credit, the European Parliament (STOA), the Joint Research Centre, DG Research & Innovation and DG Justice & Consumers have recognised the year-on-year value of engaging with a unique group of global health advocates assembled on their doorstep. To give just a couple of examples

of positive developments, DG Joint Research Centre, the in-house science service of the EU, has just created a new Unit responsible for Public Health Policy Support and is looking at harm reduction science. The EP's Science Directorate also mirrored our 2013 Consultation Event brain mapping theme as its 2014 Annual Lecture and has embarked on an exciting recruitment programme to bring scientists into the daily lives of MEPs.

The Office of the Chief Science Adviser to the President has also lent its support, inputting some excellent ideas and comments this year. Sadly, they have now been closed down, showing just how risk-averse the EU's science system really is and that if you go against the grain, it is hard to survive. The jury is still out as to whether President Juncker will address this glaring gap – let's hope so.

The dialogue between science and policy is never straight-forward, of course, but it remains the bedrock of our knowledge-based societies. This relationship is crucial. The importance of sound science is growing, providing the evidence base for sound public policy. Viewed from Brussels, we are all losers if we accept anything but the highest standards of openness and accountability from our largely non-scientific civil servants, especially around life and death issues such as substance addictions. The school report card reads ***'could do better'.***

Each year, we try to identify a topic that is perhaps the *'new black'*, one which offers great promise, but which might never see the light of day because the scientific majority feels threatened by it, or policy-makers – who generally lead from behind in science – fear it upsets the funding status-quo. The health risk for the general public through inaction might be enormous. In advocating this brand of ***'science in the public interest',*** SciCom *'nudges'* thought-leaders and decision-makers to get together, have a re-think and ideally, *'to do the right thing'*, as former EU Chief Science Advisor Anne Glover framed it in 2012.

SciCom's role is to simply add value to the discussion by facilitating it in the first place. Our network of science diplomats passionately believes that science and scientists have a special claim to be heard, provided they are committed to:

- **INTEGRITY:** to uphold the inherent honesty of scientific enquiry and debate;
- **OPENNESS:** to keep the lab door open, and making clear any special interests;
- **CLARITY:** to speak in terms the public can understand; &
- **ENGAGEMENT:** to demonstrate that they take their duty to society seriously.

On behalf of myself as Convenor, and Co-Chairs Professor Kazatchkine and Professor Kinderlerer, we encourage you to find out more about how this ***SciCom Addictions Series*** is put together online at www.sci-com.eu and to follow us on Twitter@SciComEU. We leave you with the fifteen guiding principles that our ***Consultation Event*** participants have identified as fundamental to the ***harm reduction science and policy relationship.***

SCIENCE AND POLICY – A CRUCIAL RELATIONSHIP

1. Science is a fundamental pillar of knowledge-based societies;
2. Science can help provide the evidence base for sound public policy;
3. The dialogue between science & policy is never straight-forward but remains a special relationship;

WHAT WE EXPECT FROM THE SCIENTIFIC COMMUNITY

4. The integrity of science needs to be positively asserted & defended;
5. Stronger emphasis must be given to the inclusion of social sciences to improve understanding of how the public may react or adapt to lifestyle challenges;
6. Scientists must learn to use established communication channels for providing policy advice more effectively, especially on life-or-death issues;

WHAT WE EXPECT FROM THE POLICY-MAKING COMMUNITY

7. Policy-makers must be receptive to scientific advice, even when this advice is uncomfortable;
8. For the science & policy relationship to work, policy-makers have to challenge science to deliver on their public investment;
9. Policy-makers should consult more widely and learn from best practices & pitfalls encountered elsewhere;

WHAT WE EXPECT FROM THE PUBLIC, INDUSTRY & INTEREST GROUPS

10. The public plays a critical role in determining what positions policy-makers will take;
11. Industry is the largest investor in science and has every right to have its voice heard;
12. Interest groups similarly have every right to have their voice heard as guardians of the common good or legitimate sectoral interests;

WHAT NEEDS TO HAPPEN

13. Scientific advice must be more involved in all stages of the policy-making cycle, particularly in brain reward research;
14. Policy-making must learn to cope with the speed of scientific development & include greater foresight & policy anticipation;
15. Investment in substance addictions science & their brain reward systems is *"the right thing to do".*

WORKING GROUPS

WHAT SHOULD WE EXPECT FROM THE SCIENTIFIC COMMUNITY?

- **Discussion Lead: Dr. Mary Baker,** *Consultant to the WHO & Adviser to the European Union*
- **Dr. Gert-Jan Meerkert,** *Senior Researcher, Behavioral Research Addictions Institute, Erasmus University, Rotterdam, The Netherlands*
- **Dr. Eva Woelberg,** *Scientific Officer, European Commission, Public Health Unit, Institute for Health & Consumer Protection, Joint Research Centre*
- **Dr. Gerard Dubois,** *President of the Committee on Addiction, French Academy of Medicine*
- **Ms. Agnieska Katner,** *Public Affairs Manager, Pernod Ricard*
- **M.D. Kevin Bridgman,** *Chief Medical Officer, Nicovations Ltd*
- **Prof. Roy Robertson,** *Centre for Population Health Science, University of Edinburgh*
- **Dr. Francis Crawley,** *Executive Director, The Good Clinical Practice Alliance Europe*
- **Mr. Bruce McCallum,** *Science & Innovation Counsellor to the EU of the New Zealand Ministry of Business, Innovation & Employment*

WHAT ARE THE FACTORS TAKEN INTO ACCOUNT BY THE POLICY-MAKING COMMUNITY & WHY?

- **Discussion Lead: Professor Julian Kinderlerer,** *Chairman, European Group on Ethics in Science & New Technologies (EGE)*
- **Dr. Jan-Marco Mueller,** *Assistant to Prof. Anne Glover, Chief Science Adviser to President Barroso, Former Assistant to the Director-General, Joint Research Centre*
- **Mr. Daan du Toit,** *Deputy Director General, International Relations, South African Ministry of Science*
- **Ms. Ann Cahill,** *President of the International Press Association, Europe Correspondent, Irish Examiner*
- **Dr. Theo Karapiperis,** *Head of Unit, Science & Technology Options Assessment (STOA), Directorate-General, European Parliament Research Services*
- **Dr. David O'Reilly,** *Group Scientific Director, British American Tobacco*
- **Prof. Ritva Tuulikki Halila,** *Hjelt Institute, University of Helsinki & Member of the European Group on Ethics (EGE) reporting to President Barroso*
- **Dr. Bogosi Mogale,** *Health Attaché, South African Mission to the EU*
- **Mr. Isidoros Karatzas,** *Head of the Ethics Sector, European Commission, DG Research & Innovation*
- **Dr. Peter Tindemans,** *Secretary-General Euroscience, Former Director, Research Council of The Netherlands and Academy of Sciences of The Netherlands*

WHAT NEEDS TO IMPROVE FROM THE PERSPECTIVE OF THIRD-PARTIES & INTEREST GROUPS?

- **Discussion Lead: Ms. Nathalie Moll,** *Secretary General, EuropaBio*
- **M.D. Lars-Eric Rutqvist,** *Senior Vice President Scientific Affairs, Swedish Match*
- **Ms. Cecilia Iturralde,** *South African Mission to the EU*
- **M.D. Delon Human,** *CEO Health Diplomats, Secretary-General of the African Medical Association*
- **Mr. Paul Skehan,** *Director-General, Spirits Europe*
- **Mr. Simone Boselli,** *Vice Chair, Healthcare Committee, American Chamber of Commerce EU (AMCHAM)*
- **Ms. Paola Tardioli-Schiavo,** *Deputy Head of Unit, European Commission, Anti-Drugs Policy Unit, DG Justice, Fundamental Rights & Citizenship*

HOW SHOULD SCIENTISTS, POLICY-MAKERS & THIRD-PARTIES WORK TOGETHER TO MANAGE RISKS & UNCERTAINTIES AT THE SAME TIME AS PROMOTING INNOVATION?

- **Discussion Lead: Prof. Didier Jayle,** *Professor of Addictology, National Conservatory of Arts & Metiers, France*
- **Prof. Jean Francois Etter,** *Institute of Global Health, Faculty of Medicine, University of Geneva*
- **Ms. Charline Pierre,** *Science Journalist, Belgian French-Speaking TV (RTBF)*
- **M.D. Michel Kazatchkine,** *UN Secretary-General Ban-ki Moon's Special Envoy on HIV/AIDS to Central Europe and Central Asia, Member of the Global Commission on Drug Policy*
- **Dr. Vittorio Prodi,** *Former Member of the European Parliament, Committee on Industry, Research & Energy (ITRE) & Science & Technology Options Assessment Panel (STOA)*
- **Dr. Simon Planzer,** *Faculty of Law St Gallen University Switzerland, Harvard medical School & European Journal of Risk Regulation*
- **Dr. Didier Schmitt,** *Scientific Adviser & Foresight Coordinator, Chief Scientific Adviser Team to President Barroso, Bureau of European Policy Advisers (BEPA)*
- **Dr. David Budtz Pedersen,** *Humanomics Research Centre, University of Copenhagen; Strategic Adviser, Danish Ministry of High Education & Science*
- **Mr. Frederik Wittock,** *Director, R&D Communication, Janssen Pharmaceuticals*

HIGH-LEVEL CONSULTATION EVENT JUNE 2015

Scicom is pleased to announce: ***Addictions: Regulating Risk*** as the 2015 theme. The fourth in this health series, it will be Chaired by Professor Julian Kinderlerer, University of Cape Town and President of the European Group on Ethics in Science and New Technologies (EGE,) reporting to European Commission President Juncker, and the European Parliament.

CONSULTATION EVENT 2014

Event Co-Chair: Professor Julian Kinderlerer

Consultation Event Working Groups

Networking Cocktail

Professor Michel Kazatchkine & M.D. Delon Human

Dr. Didier Schmitt & Dr. Theo Karapiperis

Professor Didier Jayle & Dr. Mary Baker

Prof. Julian Kinderlerer (SA), CONSULTATION EVENT CO-CHAIR, President of the European Group on Ethics in Science and New Technologies (EGE) reporting to European Commission President Juncker and the European Parliament; Prof. of Intellectual Law, Cape Town University; Adviser to the South African Science Ministry; Occasional Adviser to the UN Environment Programme; UN Industrial Development Organisation; World Intellectual Property Organisation; Former Director of Institutes on Biotech Law, Ethics & Society at Delft and Sheffield Universities.
URL: http://tinyurl.com/kdo3tb4 Email: Julian.kinderlerer@uct.ac.za

THE ETHICS OF INTERVENING IN THE LIVES OF SUBSTANCE ADDICTS

How do we differentiate between the responsibilities of individuals to look after themselves within an evermore complex social structure, and the responsibilities of States to look after their citizens, provide security and a milieu in which to live a satisfying life? If an individual wishes to take actions that may harm themselves but debatably have no impact on the lives of others, such as smoking, vaping, drinking or taking illicit drugs, should the State interfere? Can a rational analysis based on robust science provide a more effective basis for assuring that individuals are treated with respect and fundamentally that society ensures that individuals are not interfered with when causing no harm to others?

ARE WE REALLY INDIVIDUALS ANYMORE?

The way in which our lives are interwoven means that most of our actions do impact on others in ways that are difficult to unravel. If an individual chooses to end their own life, by whatever means, the impact on others is not negligible. If one smokes cigarettes, the harm to our own health is well-documented and clear, there is also harm to the health of others and the impact on health services is huge. Should society tolerate this burden in order to protect the rights of the individual? An example of the problems of addressing the rights of the individual and that of society in assuring their well-being is that of legal and illegal drugs. Taking mind-altering drugs is almost a norm in many societies even where it is frowned on by officialdom and is illegal. There are many contradictions in the manner in which society handles the affairs of those who form part of the *'group'.* We talk of the rights and responsibilities of citizens and how important the individual is in society, but the **inconsistencies in treatment of various actions are manifest.**

In some cases interference with the right of accredited physicians to prescribe drugs that could be harmful to patients is deemed unacceptable, yet the physician has a responsibility to do no harm! Misuse of prescription drugs in most countries accounts for more deaths per annum than the use of *'banned'* or illegal narcotics. The abuse of prescription drugs may result in more hospital admissions than the use of illegal drugs. In 2013, nearly 700,000 Americans dosed themselves with heroin. It is thought this is a result of the higher cost of prescription

opiates *(and other drugs)* that are abused by as many as 11 million Americans annually![7]

Many currently illegal drugs, such as marijuana, opium, coca, magic mushrooms and psychedelics have been used for thousands of years for both medical and spiritual purposes, but our legislation at worst treats users as criminals. Legal mind-altering drugs, like tobacco and alcohol result in massive strains on the health of individuals misusing them and on medical services, and alcohol can be implicated in much criminal activity and harm to others.

RELIGION & INTOXICANTS

In strict Muslim societies the use of intoxicants is totally unacceptable, whether alcohol or mind-altering drugs *(like cannabis or hashish)*. These are said to be the *"most terrible of all major sins"!* An example of the teachings is that which Sheikh Taymiyyah wrote of Hashish[8]:

1. ***"From a religious point of view it is as intoxicating as wine, it destroys the mind, causes forgetfulness, causes to reveal secrets, destroys shame, incubates dissimation, quells self respects, obliterates intelligence, prevents salaah and instigates towards Haraam, forbidden things."***
2. ***"From a physical aspect it deteriorates the mind, cuts off the means for offspring, brings about leprosy, sickness, feverish shivers, bad breath, loss of eyebrows and teeth, warming of blood, tuberculosis, damages intestines, destroys body organs, punctures the liver, burns the stomach and weakens eyesight amongst other things."***

Intoxicating substances in strict Muslim societies are therefore forbidden, for they demean the dignity of the human, rather than taking into account the impact on others. Though the prohibition of illegal drugs was established under Islamic law, particularly against the use of hashish as a recreational drug, classical jurists of medieval Islamic jurisprudence accepted the use of hashish for medicinal and therapeutic purposes, and agreed that its *"medical use, even if it leads to mental derangement, should remain exempt [from punishment]"*. In the 14th century, the Islamic scholar Az-Zarkashi spoke of *"the permissibility of its use for medical purposes if it is established that it is beneficial."*[9]

Judaism values life above all else. The recognition of harm done by tobacco has led to censure of those using it, even though many strict adherents to Jewish thought and philosophy still do so through a smog of tobacco. Some rabbis insist that the requirement to protect life at all cost means that smoking is a sin. Alcohol remains an acceptable part of Judaism, used in many rituals as it is in Christian worship. Indeed, the psalms refer to wine as something that *"gladdens human hearts"* – *"wine that maketh glad the heart of man, making the face brighter than oil" (Psalm 104:15)* and complete abstinence has been regarded within Jewish literature as turning away from civilisation *(Jeremiah, 35)*. Its toleration, however, is not a toleration of drunkenness – for biblical writings warn that drunkenness brings poverty, woes, quarrels, wounds, strange visions, etc. *(Prov. 20:1; 21:17; 23:19–21:29–35; 31:4–5)*.

Christianity initially held that both the Bible and Christian tradition taught that alcohol is a gift from God that makes life more joyous, but that over-indulgence leading to drunkenness is sinful or at least a vice. Medieval monks were well known as

brewers and vintners and were allotted about five litres of beer per day, and were allowed to drink beer *(but not wine)* during fasts.[10]

In Western societies many drugs are seen as dangerous and their use intolerable. Indeed, some of the drugs that have been banned may have medicinal use but in much of the world either cannot be prescribed or their use is heavily proscribed due to the possibility of misuse. Other *'drugs'* that may have more harmful effects are accepted as not only normal, but individuals who choose not to partake are often hounded or treated with scorn. There are many double standards – cannabis is used by millions world-wide *(The Economist estimates that more than 3 million US residents use it annually)*[11].

HOW MAY WE ADDRESS THE RIGHTS & RESPONSIBILITIES OF CITIZENS AS INDIVIDUALS & THEIR RIGHTS AS PART OF A SOCIETY? SHOULD SOCIETY STEP IN & REQUIRE INDIVIDUALS TO ACCEPT NORMS REGARDLESS OF THEIR OWN BELIEFS?

The Charter of Fundamental Rights of the European Union[12] provides a basis for an **ethical perception of our lives** in the modern world. It places human dignity, freedom, equality and solidarity as fundamental principles, and recognises the concepts of democracy and the rule of law as the mechanism for ensuring that these principles are implemented.

The Universal Declaration of Human Rights[13], only agreed after the end of the Second World War, states: *"recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world".* The first Article provides: *"All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood."* Article 12 of the Declaration provides: *"No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honour and reputation. Everyone has the right to the protection of the law against such interference or attacks."*

Dignity is a concept that is used glibly. It is used in many different ways, from a concept of human worth to protecting the rights of those unable for many reasons to protect themselves. It includes a concept of respect and seems to provide a measure of human worth or status. It is easier to define that which impacts on human dignity than to identify all that the concept includes – torture, humiliation, dehumanisation, degradation and instrumentalisation all conflict with this concept. If humans have dignity, then they need to be treated with respect. Human dignity is related to human agency, the ability of humans to choose their own actions but to act responsibly.

Autonomy arises from the concept of dignity as the capacity of a rational individual to make informed, un-coerced decisions. We also speak about autonomy glibly, providing a mechanism for individuals to look after themselves without interference from an overbearing state – arguing that we can do as we wish to ourselves as long as it does not interfere with the rights of others to do exactly the same.

This autonomy is a powerful argument for the rights of individuals, but how far can it be allowed to impact on the lives of citizens? We are able to smoke cigarettes

and drink as much alcohol as we can tolerate in most non-Muslim countries, but are not permitted to commit suicide in many countries. Indeed, suicide has traditionally been a crime. Attempting suicide in India, for example, is a crime which could lead to a sentence of a year's imprisonment. Millions take prescription drugs and millions die from the misuse of such drugs, but drugs that alter the perception of reality are criminalised and disallowed in most countries. How do we justify the involvement of the State in deciding which mind-altering or mood-altering chemicals we may use and the manner in which we choose to express our individuality within the overall governance within which we live?

Many countries have attempted to introduce laws restricting the use of alcohol, but it became clear in most cases that this was counterproductive as illegality and criminality increased. These included: the United States *(1920–1933)*, Finland *(1919–1932)*, Norway *(1916–1927)*, Canada *(1901–1948)*, Iceland *(1915–1922)* and the Russian Empire/USSR *(1914–1925)*.

Towards the end of the twentieth century the use of punitive taxes and public information strategies desperately tried to reduce the use of tobacco and sometimes alcohol without criminalising their use, except in most circumstances their use in public spaces where use could impact on others has been banned or criminalised. One only has to think of policies today regarding the cultivation of cannabis for personal use in Belgium or the Netherlands, or the EU's blanket sale ban, but not usage ban, of snus oral pouch tobacco outside Sweden.

BANS HAVE HISTORICALLY FAILED

In the United States, there are many who argue that the power of the Government is far too great, and the role of the State in governing people's lives should be restrained and reduced. Yet, it was in the United States that the prohibition movement gained a powerful foothold at the beginning of the twentieth century, leading to the constitutional amendment that made illegal the production, transport and sale of alcohol. This constitutional change meant that alcohol was difficult to obtain anywhere in the United States between 1920 and 1933 *(although possession and consumption were not themselves offences)*. At the time alcohol was *'illegal'* but cannabis was not! Laws *'banning'* opiate drugs were initiated in the United States in 1906 under the food and drugs act, which required labelling of foods that contained dangerous substances – alcohol, morphine, opium and cannabis were included in the list of dangerous drugs. Their use was not illegal, but products containing them had to be labelled *(use did not have to be safe, merely labelled so that individuals had a choice)*.

The International Opium Convention (1912) called for the following: *"The contracting Powers shall use their best endeavours to control, or to cause to be controlled, all persons manufacturing, importing, selling, distributing, and exporting morphine, cocaine, and their respective salts, as well as the buildings in which these persons carry such an industry or trade."* This Convention was incorporated into the treaty of Versailles, ending the First World War. Nevertheless, an editorial in the *Illinois Medical Journal* for June 1926, after eleven years of federal law enforcement, concluded:

"The Harrison Narcotic Law should never have been placed upon the Statute books of the United States. It is to be granted that the well-meaning blunderers who put it

there had in mind only the idea of making it impossible for addicts to secure their supply of "dope" and to prevent unprincipled people from making fortunes, and fattening upon the infirmities of their fellow men. As is the case with most prohibitive laws, however, this one fell far short of the mark. So far, in fact, that instead of stopping the traffic, those who deal in dope now make double their money from the poor unfortunates upon whom they prey. . . ."

The *'cultural revolution'* of the 1960s brought the problem of mind-altering drugs into the realm of politics. Drugs were becoming a tool to show dissent to the status-quo, and were a means of showing political dissent. **Many of those drafted to Vietnam returned having developed a drug habit that concerned many in the political establishment.**

In June 1971, President Nixon in the United States declared a *"war on drugs"*, the effects of which have been far-reaching and which my Co-Chair, Professor Kazatchkine, deals with subsequently. Nixon dramatically increased the size and presence of federal drug control agencies, and pushed through measures such as mandatory sentencing and no-knock warrants. Nixon temporarily placed marijuana in Schedule One, the most restrictive category of drugs, pending review by a commission he appointed led by Republican Pennsylvania Governor Raymond Shafer.

In 1972, the commission unanimously recommended decriminalising the possession and distribution of marijuana for personal use. Nixon ignored the report and rejected its recommendations. When Reagan took office, the number of people behind bars for nonviolent drug law offenses increased from 50,000 in 1980 to over 400,000 by 1997.

What exists, therefore, is a system which penalises those who use some drugs deemed by politicians as detrimental to society in a manner which is both inconsistent and which has increased criminality both by drug uses desperate to *'get their next fix'* and by those running the illegal business of supply. This criminality is evident in Mexico which has succumbed to virtual anarchy in attempts to control the supply of drugs.

Those using illegal drugs include the young rebelling against a perceived unjust society, the socially inadequate who feel they need to escape from reality and even those whose lifestyles are so stressful that an escape is a way to express themselves away from their normal everyday existence.

The UK Commission, which looks only at illegal drug use, suggests that we need to look at *"how society and government can enable and support individuals to behave responsibly. This means tackling underlying causes of drug use, providing the information and skills necessary for people to make sensible choices about drug use, and ensuring that where drug use does occur, it is undertaken in a way that minimises the harm to the user and others."*

The Drug Policy Commission in the UK (2012) states that:
"Drug policy is currently a mix of cautious politics and limited evidence and analysis. This is coupled with strident and contested interpretations, both of the causes of problems and the effects of policies. In fact, for as long as there has been a drug policy, there have been gaps in the evidence as well as uncertainty about how to understand and act on the evidence that we do have.

They further state that *"What we mean by 'responsible behaviour' is that an individual should seek to behave in ways that allow them to achieve their potential and contribute positively to their families and communities and also to avoid incurring harm to other people in general. Behaving responsibly and limiting harm and damage to oneself and others are two sides of the same coin."*

GETTING THE INTERVENTION BALANCE RIGHT

My personal conviction is that society both professes intolerance for the use of *'drugs'* and provides the social settings to enable and make legitimate their use. It is abundantly clear that the *"war on drugs"* has failed. There is a need for a rational policy that addresses the rights of the individual, the needs of society to assure that we respect each other without imposing the views of some on the rights of all.

Policies on drugs cannot simply allow a free-for-all. We already restrict use of tobacco and alcohol. There is a need for a rational approach, addressing the needs of many to opt out, for a short time, from the realities around them *(on condition that harm to others is not done)*, and assuring that addiction is properly addressed within a health service rather than through the criminal law.

International efforts should be directed towards developing a kind of framework that would control the *"supply of all psychoactive substances, including alcohol, tobacco and solvents, as well as other drugs that are used for cognitive, appearance or performance enhancement … This would provide an opportunity to remove anomalies that have grown up over the years."*

The free-for-all of the 19th and early 20th century, in which individuals like Sigmund Freud and Arthur Conan-Doyle were allowed to overdose on drugs like cocaine is long over. Conan-Doyle wrote of Sherlock Homes as *"alternating from week to week between cocaine and ambition, the drowsiness of the drug, and the fierce energy of his own keen nature"*. Recognition of the harm done by drugs, and the need of so many for these drugs is long overdue. Rationality in our approach to all mood and mind altering drugs is needed. The Illinois Medical Journal got it right – *"those who deal in dope now make double their money from the poor unfortunates upon whom they prey. . . ."*

Scientists and ethicists must step in and inform those who make policy of the harm being done to all concepts of law when those who are governed hold it so much in contempt. ***Addictions: Regulating Risk*** will be the theme of our ***2015 High-Level Consultation Event*** when we hope to unite some of the best minds around to address this ongoing challenge.

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PROVIDING SCIENCE ADVICE TO GOVERNMENTS: CASE-STUDIES IN TEENAGE MORBIDITY AND RECREATIONAL DRUGS

At the first global meeting on the practice of providing science advice to governments, held in Auckland in August 2014, there was broad recognition that there are multiple modalities of science advice including both deliberative *(formal)* and informal processes[17]. Where the evidence is of a complex or contested nature formal processes are essential, but to be effective, any system intended to ensure the input and integrity of scientific evidence into policy also requires informal processes. Not only do these two sets of processes differ from each other, but they are also quite separate from the goal and practices of providing policy for the science system per se. Yet these concepts and modalities are often conflated in the minds of the public, of government and, indeed, of the science community.

HOW SCIENCE POLICY-MAKING USUALLY WORKS

Formal deliberative inputs may come from an academy or a commissioned panel of experts or, in some cases, from government experts within a ministry. Academies may choose to undertake studies on their own account or they may be requested to do so by policy makers. However, when they do it on their own account they may be somewhat disappointed that their work may not have the impact they had hoped, for it may be answering questions that are not asked by the policy process and are not perceived as being needed. Generally, the robust independence of academies provides confidence in the products of their work, whether such studies are self-initiated or commissioned by governments. The use of ad–hoc or standing committees of experts, provided they are appropriately constituted and conducted, offer a similar level of assurance.

One key consideration with regard to such formally constituted and deliberative

science advice however, is the prescribed timing of the committee's or panel's input into the policy process. This is either quite early *(horizon scanning and foresighting)*, or late in the policy process *(as decision makers await expert input)*. In either case, the input nearly always occurs at a single point within the policy cycle, yet the need for evidence and its use often evolves throughout the cycle.

Policy formation is a complex iterative process between policy analysts/advisors, subject matter experts, politicians and external stakeholders. It is easy for science to be quickly ignored or separated from other considerations. Yet the essential need is to try and ensure the place and integrity of science-based input throughout the process. In my view, this is a particular role best served by individual ***'evidence champions'*** such as science advisors who are mandated within the policy process, yet remain positioned with a level of independence from the other processes of government. This is important.

Such informal advice has many other purposes. More often than not, the genesis of policy ideas is found within the informal conversations that politicians will have with colleagues, counterparts, and constituents. Sometimes, these ideas are supported by a recognised evidence base, but often they are not. In my experience this is where the individual science advisor can act as a foil and provide a challenge function. She or he can provide a safe and knowledgeable ear on which to test ideas and sharpen questions. The advisor can remind others of the data and evidence and flag any issues that the evidence may point to about the various policy options. That informal interaction may be the most important – but often unrecognised – component of the science advisory system.

Public servants who are technical experts play an important part in policy development and can also serve to protect the integrity of science-based advice. However, depending on the culture of the department, this type of internal expertise is often quite removed from the final decision-making machinery or the science too easily is integrated with other elements of the policy process and key points can be lost, as it is subject to filtering across the policy process.

Yet, increasingly it is becoming clear that science should have a privileged place in the policy process, that many areas in which policy- and law-makers are now called upon to act require the benefit of science. Robust scientific input is the only reliable way to understand what is known about many issues, what is not known and what are the likely implications and trade-offs of the policy options being explored. Once these elements are clearly delineated, it is the job of the decision-makers to weigh the trade-offs and to make values-based judgments, which require many other inputs, about one course of action over another.

While it is accepted that science itself is not values-free, the values associated with science *(i.e. choice of methodology and analytical framework or judgments on the sufficiency of evidence for instance)* are quite distinct from the values associated with policy-making, such as of public opinion and political ideology. Ideally government departments should have processes to protect the integrity of the evidence through this imprecise and shifting policy process. In New Zealand this will be a key role of the growing cadre of departmental science advisors now being appointed.

Two recent experiences in New Zealand highlight the relevance of a mixed model of formal and informal science advice with iterative capacities. The second case also highlights the limitations that the scientific community must accept as a reality of democracy.

EXAMPLE 1: TEENAGE MORBIDITY

In 2009, a new Government was elected in New Zealand. The new Prime Minister himself shared the public's concern over the high rates of teenage morbidity and mortality in New Zealand's multicultural society, the statistics on which are alarming by international comparison. Within the OECD, New Zealand youth had the highest rate of suicide, the second highest rate of teenage pregnancy and there was high public concern over alcohol and drug usage and teenage crime statistics. The media interest was acute and clearly calling for action.

The conventional approach in New Zealand would have been for a multi-agency and multi-stakeholder working group to be established and to then report on the issue. In all likelihood, its outcomes would have represented the inputs of the various vested interests and little progress would have been made, given that in such issues every person and stakeholder has a strong view as to what the solution should be.

Instead, the Prime Minister approached me, as the country's first Chief Science Advisor (CSA) for my view on how to proceed. I recommended that as a starting point we establish a committee of academic experts to review the literature and **define what we actually knew about the science of adolescence and its associated morbidity.** This was agreed to. I appointed an academic co-chair who is a distinguished developmental psychologist. We approached initially 15 experts from a range of relevant disciplines to form a committee. Ground rules were established – only the peer-reviewed literature was to be considered and work that reflected a values-based or ideological position was identified and ruled out. What was intended as a 6 month process in the end took about 18 months and the panel of experts grew as new dimensions to the study were identified.

The final report[18] comprised a long summary document followed by over 25 chapters, written by members of the expert panel and associates. It was subject to international peer review. It effectively made no specific recommendations but highlighted areas of focus both with respect to early childhood experiences and the development of resilience, and regarding youth mental health and the development of the adolescent brain. Both an interim report and the final report received high media interest and led to considerable public conversation.

The Prime Minister established a senior officials group both from his Office and the relevant ministries to consider the report's policy implications. The officials recommended a comprehensive suite of new actions largely in the area of youth mental health promotion and treatment. The Prime Minister again asked me to chair a small group of relevant academics to review the policy recommendations. *(As it happened,*

this group had some strong views about one potential class of approach that had been omitted by officials, which I shared with the Prime Minister in informal discussion. As a result, the deficiency was remediated and consequent modifications were made in the final suite of activities for him to consider).

Throughout this policy formation process it was the report of the academic experts and then of both the officials and the academic review group that made it clear that the problem was complex and implied that **there would be significant uncertainty as to which, if any, of the proposed interventions would be effective.** The academic review group advocated for the continual monitoring and evaluation of interventions once implemented – something that is not always common practice within government.

The Prime Minister subsequently announced the funding of the full suite of recommendations at a press conference and, in doing so, he acknowledged that this choice of interventions was based on the best evidence available but their effect would be uncertain and warranted concurrent monitoring and study. In my experience, it is unusual and very healthy for a politician to announce a major initiative without making claims about its expected success. In this case, the Prime Minister was calling for nothing short of a robust policy intervention trial, with multiple activities being tried in parallel and subject to evaluation. This was again well received by the media and suggests that **well-framed evidence-informed policy formation of uncertain impact even in complex areas is perfectly *(if not more)* acceptable to the public and is refreshingly devoid of political hubris.** The evaluation process for these programmes is now underway by an independent agency.

In this example there are several important principles in play. The process was initiated because of an informal interaction between the Prime Minister and a trusted independent science advisor and led to a quite different process than what otherwise would have emerged. This led to a very extensive deliberative exercise with rigorous separation of the science from non-scientific values based arguments. The policy analysts were then able to take this and use it as the basis of developing recommendations for action. But again it took shepherding by the science advisor to protect the integrity of those recommendations to the point of final decision-making. The political upside of evidence-informed policy formation in a complex and highly charged area was that any contentious debate was readily diffused by a focus on a suite of actions, the possible outcomes of which were not exaggerated by the political process.

EXAMPLE 2: RECREATIONAL DRUG USE

New Zealand, like most countries, had taken a standard prohibitive approach to recreational psychotropic drugs – namely grading them for their perceived risk of harm and addiction and then specifically listing them in legal schedules with a proportional range of penalties. However, with the advent of synthetic cannaboids, many potentially harmful agents effectively escaped regulation. **An arms race was underway between the chemists and the regulators that the regulators could not win.** At the same time

there was mounting evidence and growing concern at the number of young people being admitted to emergency rooms with acute drug-related psychotic events. That is when a member of the [then] coalition government proposed a bold experiment: to reverse the approach by proposing to ban all such agents unless they were proven to be *"safe"* according to regulations to be administered by the Ministry of Health *(put another way, it was legalising those recreational psychoactive agents that could meet rigorous safety standards)*. This approach rapidly gained traction at least in principle, but the debate became politicised when it came to defining the *"sufficiency of evidence"* for safe use and its codification into law.

The proponents of liberalising recreational drug use had argued for a lower standard of proof than would be needed for a medicinal pharmaceutical agent, arguing that the state of synthetic chemistry was such that *in vitro* testing would be sufficient. Those with experience in pharmacology, by contrast, argued that animal testing in two species was needed, including some forms of acute and chronic toxicology measures. My Office was consulted by both the Ministry of Health and by Ministers. I advised that if the State was to give some affirmation of relative safety of new psychoactive substances, a pharmacological approach would be required and in the current state of knowledge, some *in vivo* testing in animals was unavoidable. Ministry officials concurred with this view.

At this point, both the political and popular discourse rapidly shifted from the role of the State in ensuring the relative safety of approvable agents, to the question of testing recreational drugs in animals. The use of animals in research and development is highly emotive and there was no political appetite for expanding safety testing in animal models beyond therapeutic agents. While some toxicologists had argued that sufficient evidence could be collected via rodent tests alone *(i.e. avoiding larger animal species such as dogs)*, even that more restricted definition of sufficiency of evidence became an emotive discussion. The parliamentary select committee handling the Bill sent it back with amendments that banned animal testing. With the relevant drug safety committee of the Ministry of Health requiring animal testing to certify a pharmacological agent as fit for human use, the outcome was effectively a total ban on the recreational use of synthetic psychoactive agents.

It is not clear whether the parliamentarian who started the debate on animal testing did so with the calculated intention of this total ban. In any event the outcome has been that the country has ended the race between chemist and regulator.

The nature of the debate in this case rapidly shifted from an evidence-based and strictly values-based discussion on the use of animals in drug testing. The scientific advice and practice did not change and the practical outcome was a total ban. It is clear that the appeal to science in this case offered considerable collateral political benefit: politicians appeared sympathetic to a liberal approach, they emphasised concern for public safety *(especially the youth market for the drugs)*; they were sensitive to societal concerns about animal testing, all while achieving an effectively total ban, without being seen to be heavy-handed.

LESSONS LEARNED

These two examples highlight some key points about the use and limits of science

advice and the ***realpolitik* of policy formation in emotionally charged areas.** The first example demonstrates that they are major areas of complex policy development where science advice can play an important role. But it also demonstrates the synergistic roles of informal and formal advice. It is difficult to imagine the counterfactual wherein the Academy writes an unsolicited report on adolescence and this leads to major government action. Nor would such a scenario create the nexus of interaction between scientist, policy maker and politician that led to action. But while informal processes were essential to the initiation and to ensuring integrity in the latter phases of policy formation, the deliberative formal approach was essential to there being trust and validity to the outcomes achieved.

The second example highlights something quite different: there are instances where science may seem key to resolution, when in reality it is marginal to the larger political process. However marginal, in this case it was the integrity of science *(i.e. insisting on animal testing*) that effectively resolved the values-based debate.

In a democracy there will always be a complex interplay between science and societal values. Successful science advice requires that those individuals or committees acting in the boundary roles between the two worlds of science and policy appreciate the difference between scientific values about methods and the sufficiency of evidence, and societal values. When they enter the world of societal values their voice may be informed by science but they have no more status than any other citizen. Policy makers rightly get concerned (even angry and dismissive of science advice) if those with such intermediary responsibilities are seen to usurp the policy maker's role as arbiter of the trade-offs between different societal values and concerns.

This distinction is not always easy to make and the further distinction that needs to be appreciated is between the rights of the individual scientist as a citizen and those who have specific intermediary roles to play in advising governments. As Roger Piekle[19] has pointed out, **individual scientists can and do act as advocates but those in advising roles need to act primarily as honest brokers of knowledge.** As science is increasingly called upon to assist society in many complex and contentious areas, it is important to understand how the worlds of advocate and honest broker interact and, in some cases, collide. Perceptions of hazard, risk, vulnerability and precaution often vary between the public, the science community and politicians. Any science advisory mechanism must take this into account.

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MAPPING THE BRAIN, UNLOCKING THE MIND, TACKLING ADDICTION

The *'Brain Age'* is upon us. The race is on as we enter a new chapter in human history. Massive global investments in brain research and cognitive neuroscience from Beijing to Boston to Brussels are transforming our understanding of the human mind. The European Union's Human Brain Project[20] aims to develop new technology platforms dedicated to Neuroinformatics, Brain Simulation, High Performance Computing, Medical Informatics, Neuromorphic Computing and Neurorobotics. The United States' Brain Initiative[21] aims to understand the human brain and how individual cells and complex neural circuits interact in both time and space. These are just two of many bold new research efforts to revolutionise our understanding of the human mind and uncover new ways to treat, prevent and cure brain disorders like Alzheimer's, schizophrenia, autism, epilepsy, and traumatic brain injury.

Advocates argue convincingly that a greater understanding of the human brain holds great promise for better prevention, diagnosis, treatment, care and rehabilitation of brain disorders. We save and improve lives. Sceptics worry about the social and ethical implications of altering brain function.

In much of the world we now recognise the real value antidepressants and antipsychotics can make to the lives of those with mental illness. Drugs are available that improve attention in those with attention deficit hyperactivity disorder (ADHD). Of course, some with no need other than to excel at sport, in the exam room or workplace use pharmacological agents to improve their performance, *'cheating'* both physically and mentally. Others seek excitement and recreation in legal *'highs'.* Science allows us

to modulate and manipulate brains, bodies, our moods and actions. It can bring relief to those who are ill and challenges to society as a whole.

The complexity of understanding brain function and brain disease brings responsibilities as well as opportunities for the neuroscience community for the benefit of society. Despite these major challenges and all the efforts of the scientific community, we are still struggling against the discrepancy between the huge societal impacts of brain diseases on the one hand, and the modest financial and time resources allocated for brain research, teaching and the care of brain diseases, on the other.

There is no way to escape from the fact that **brain disorders are a major public health challenge.** An analysis of the health economic studies of brain diseases in Europe, published by the European Brain Council in 2011, led to an estimate of **€798 billion for the total cost of brain disease in Europe in 2010.** This burden is bound to grow, largely because of the fact that the European population is rapidly ageing. Addressing these large costs requires intensified research, both basic and clinical, and the creation of novel solutions. Far too often is seems that different disease types are pitched against one another in a fight for existing research resources. We need to think about brain disease differently and keep our focus on the costs to society of not finding solutions. Without good brain health, function on so many levels can be impaired, and individuals often become unable to care for themselves properly. This inability to feed, wash or manage their comorbidities properly can quickly lead to reliance on others and the loss of independence, resulting in spiralling health economic costs. In this regard, we welcome the new initiative of the European Commission known as *'The Semester'* which will highlight the importance of demonstrating the outcomes of interventions – ***'better outcomes with better data'.*** This is the new focus for all future projects and research.

WE NEED TO APPLY COMMON SENSE & THINK OUTSIDE THE BOX

We must also beware, however, of relying more and more on prescriptions to deliver public health benefits rather than **empowering individuals to change their lifestyles.** Up to 60% of the UK's health-spend goes on treating conditions rooted in poor lifestyle choices. Health education has helped many, particularly those from the more privileged strata in society, but as of March 2012 we still recorded a smoking prevalence of 28% in Europe, including 29% of young Europeans aged 15 to 24 years.[22] The growing morbidity and mortality associated with obesity and Type II diabetes is a health tsunami just waiting to happen. We cannot tackle every addiction and their brain reward systems here. However, one of the clear messages to come out of our **High-Level Consultation Event** convened by *SciCom* is that if we do not place education, the humanities and ethics on the same pedestal as scientific endeavour, we will fail.

We are an aging society: thanks to good science, sanitation, security, education, a fine pharmaceutical industry and excellent clinicians, **it is estimated that two thirds of the people who have ever lived to be 65 years-old in the history of mankind are alive today.** We should see the glass as half full. Nevertheless, we are only now just beginning

to factor the aged into our research. The **elderly rarely if ever feature** in clinical trials. Regulators are doing more to encourage this but there remains room for improvement. Better still, it **would be good to see governments actually fund more clinical trials themselves,** investigating issues with important implications for public health. Private researchers will logically invest in areas where profits can be made to fund them in the first place, while giving shareholder value.

When it comes to substance addictions, we must transfer some of this responsibility for society's health and the prevention of disease to society. Across the globe, morbidity associated with sexually transmitted disease, smoking, drug and alcohol abuse etc. consume a significant portion of national health funds. As a society, we are forced to allocate a disproportionate percentage of our sovereign wealth, generated by hard-working tax payers, to tackling avoidable diseases linked to our poor lifestyle choices. As Deborah Arnott points out from pages 49-54 concerning low and middle income countries, these behaviours and addictions impact the most deprived segments of society the hardest.

That is not to say that we must blame the addicted person. On the contrary, we must better understand and address through informed social policy and better science, including brain research, the causes of addiction. Key to this is establishing whether **addiction a is *'weakness'* in the individual or a brain disease?** How much is determined by our genes and how much by experiences and exposure, particularly in youth? How much is reinforced or aggravated by the peculiar pressures and stresses of modern day life?

In Volume II of this series titled ***"Addictions and their Brain-Reward Systems",*** Dr. Wilson Compton of US-National Institutes of Health (NIH) states that **addiction is a developmental disorder with an abuse trajectory that predominantly starts in one's youth.** Stunning advances in the neurosciences have shown that chronic substance use affects the brain in ways that undergird the stereotypic behavioural disruptions that characterise addicted individuals. This is because the drugs of abuse co-opt the brain's neuronal circuits necessary for insight, reward, motivation, and social behaviours. Furthermore, Dr. Compton argues that: *"These drug-induced changes are long-lasting, persisting even years after drug discontinuation, which has led to the recognition of* ***addiction as a chronic and relapsing brain disease".*** Importantly, they also point the way for the development of more effective interventions for the prevention and treatment of addiction.

Remarkable scientific advances being made in genetics, molecular biology, behavioural neuropharmacology, and brain imaging offer important new insights into how the human brain works and regulates behaviour. We can now investigate questions around addiction that were previously inaccessible, such as the role of genes and environmental factors. These really are exciting times.

In the same compendium, Professor Philippe de Witte and Mr. Andy Stonard assess what the latest research is telling us about young people's brains and alcohol. They assert that the second decade of life is a time of physical maturation and continuing development of the brain. Emotions and motivations are thought to originate in the midbrain, whereas the frontal region of the brain exerts executive function and limitation of impulsive behaviour. Adolescents are vulnerable to the feeling of invincibility when

drinking alcohol. Boys and especially girls are increasingly binge-drinking, creating problems in their daily lives. Both animal and human studies have shown that heavy drinking can cause cognitive defects, which further impair decision-making, problem solving, planning, attention and learning. Thus, **early heavy drinking can interfere with school performance and create longer-lasting behavioural difficulties.** It can also result in a wide range of costly health and social consequences, including fatal and non-fatal accidents, all types of inter-personal violence, risky sexual behaviour, academic problems and alcohol poisoning.

According to the ***WHO's Global Status Report on Alcohol & Health 2014***[23], in its 194 WHO Member States, alcohol is the world's leading risk factor for death among males aged 15 to 59 years and is linked to over 200 diseases. Those who do drink consume, on average, 17 litres of pure alcohol annually. Alcohol kills 500,000 young people under the age of 30 every year. There are more deaths among men than among women from alcohol-related causes with 7.6% of all men's deaths and 4% of all women's deaths worldwide caused by alcohol.

The ***UK's 2012 Alcohol Strategy***[24] estimates that the alcohol industry contributes around £29 billion to the UK's economy, supporting over 1.8 million jobs. That said, 44% of all violent crimes in the UK are alcohol-related and there were 1.2 million alcohol-related hospital admissions in 2010/11 alone. National liver disease has risen 25% between 2001 and 2009. The latest crime statistics show that two-thirds of 17 to 30 year-olds arrested in a city in England claim to have *'pre-loaded'.* Up to one-third of alcohol-related A&E attendances are for under 18 year-olds. Interestingly, **83% of those who regularly drink above the guidelines do not think their drinking is putting their long term health at risk.** Putting the Strategy forward, UK Prime Minister David Cameron argues that a minimum unit price of 40 pence *"could mean 50,000 fewer crimes each year and 900 fewer alcohol-related deaths a year by the end of the decade".*

New brain research, allied to a growing acceptance worldwide that the social and direct costs of addictions necessitates a **complete overhaul of our current thinking**, is thankfully, slowly but surely, changing our approach to their prevention and treatment. We would argue that brain research + education + the humanities + ethics is giving us a better-rounded toolbox of responses. More importantly, it is allowing us to re-find the little bit of compassion for the addicted person that seems to have got lost along the way.

In tandem, an increasing number of front-line experts are **challenging the notion that drinking, and indeed other addictions, is an unqualified right without any associated sense of responsibility.** It is time to not only listen to, but to apply these findings to good clinical practice. The medical community often appears distant in the treatment of addiction because training and the tools to help are poor. We are heartened by Dr. Compton's recommendation to the US National Institutes of Health (NIH) that basic undergraduate medical training, country-wide, should include more of an addictions focus. Others should learn from, and implement, his example. The pharmaceutical industry too still has much to do in developing new medications, while policy-makers should more actively encourage their development and licensing.

THE SCIENCE AND SOCIETY NEXUS REMAINS CHALLENGING

When it comes to addictions and their brain reward systems, the policy landscape is still evolving rapidly. Our *'brain age'* has just begun. Nevertheless, it is all the more crucial that scientists conduct and report their work to the highest standards. Any discovery to do with unlocking the brain or country league table of drug, alcohol or tobacco use easily makes the headlines. The air time given to confused scientific opinion undermines the real value science should bring to society and policy-making. One only has to think of the countless *'Frankenstein Science'* reports around cloning, stem cells, GMOs, fracking etc. People are often cynical: *"you can find an expert to support any position".*

The e-cigarette debate happening right now is a perfect, if not unique, example linked to nicotine addiction of how a novel and rapidly growing technology offering a smokefree delivery system has sprung up from nowhere and literally caught everybody by surprise. Across the globe, news coverage, specialised reports and political discourse have exploded on the subject. At the end of the day, this is a new technology, in an emotionally charged area, that with the right standards has the potential to save millions of lives.

According to the WHO, **one billion preventable tobacco-related premature deaths are at stake in the 21st Century.** Policy-makers should make sound epidemiological research a priority. Academics and regulators should be seeking ways to help set the required product and manufacturing standards in order to provide greater confidence without stifling innovation. Industrial researchers, i.e. those actually making the products, should also be at the table and willing to establish **a regulatory framework that brings greater assurance and transparency to the consumer.** In this way, the consumer will be able to make more informed choices, taking the right steps to improve their lifestyle as and when they are ready. Sound science, drawing on clinical, toxicological and epidemiological research, in conjunction with the social sciences must inform the e-cigarette/vaping debate.

Taking this thinking a step further, in preparation for the ***High-Level Consultation Event,*** we were both involved in a working group asked to address addiction under the microscope of ***'what do we expect from the scientific community?'*** which resulted in 6 key recommendations which we would like to share:

- **The integrity of science needs to be more positively asserted;**
- **Stronger emphasis must be given to the inclusion of social sciences to improve understanding of how the public may react or adapt;**
- **Scientists must learn to use established communication channels for providing policy advice more effectively and be less aloof and perhaps less arrogant;**
- **Scientific advice must be more involved in all stages of the policy cycle, particularly in harm reduction;**
- **Policy-making must learn to cope with the speed of scientific development and include greater foresight and policy anticipation;**
- **Investment in harm reduction science is "the right thing to do".**

Perhaps the vaping debate is a good litmus test right now for how seriously society wants to empower those with damaging substance addictions. The 2016 UN debate on global drugs policy will also be telling on how far society has evolved towards enacting the crucial 4th stage of harm reduction: **1) don't start; 2) quit; 3) don't harm people around you; & 4) don't harm yourself.**

What our Brussels discussions highlighted is that there exists in drugs, alcohol and tobacco an ethical battleground between many in policy, health and industry, built often upon contradictions not founded in science. Those who are addicted need our full support while living with their addictions and in finding more permanent solutions. We agree with our fellow thought-leaders that we must act with greater compassion in embracing and encouraging harm reduction strategies. It makes both societal and economic sense. To be successful, we need to embrace brain research, unlock the mind and tackle addiction.

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PHOTO: GCDP/Rebeca Bowring

9 out of the 22 members of Kofi Annan's Global Commission on Drug Policy:
(From left to right)
Sir Richard Branson, Kofi Annan, Ernesto Zedillo, Fernando Henrique Cardoso, Cesar Gaviria, Ruth Dreifuss, Michel Kazatchkine, Jorge Sampaio and Thorvald Stoltenberg.


Drugs
200,000 deaths annually - WHO

Prof. Michel Kazatchkine, MD, (FR), Consultation Event Co-Chair & UN Secretary-General Ban-ki Moon's Special Envoy on HIV/AIDS to Eastern Europe and Central Asia; Member of the Global Commission on Drug Policy and Former Executive Director, The Global Fund to fight AIDS, Tuberculosis & Malaria.

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CRIMINALISATION OF DRUGS: THE EMERGING GAPS BETWEEN REPRESSIVE AND HEALTH-FOCUSED COUNTRIES

Most independent studies show problematic drug use increasing. As the world debates the *'war on drugs'* and what to do next, in preparation for a special session of the UN General Assembly in 2016, it is pretty clear that the international drug enforcement regime has failed to reduce the use and harm caused by drugs. This prohibitionist approach has been a mainstay of global diplomatic relations for decades. It costs tens of billions of Euros / $ to run with many vested interests. More difficult to estimate are the health and social costs associated with addiction, mass incarcerations and the emergence of a vast criminal controlled trade. The gap between what science is telling us we should do and what is actually happening on the ground is harder for policy-makers to explain away, especially in Europe which has lost its way from a position of leadership. This imbalance between *'policy-biased evidence'* above *'evidence-based policy'* is the root cause of tens of thousands of avoidable deaths and millions of avoidable infections. There is no doubt that the policy-maker must share the blame.

Thankfully, the debate on drug policy reforms has more recently been prised open by increasing *"activism"* from opinion leaders and civil society. Harm reduction science is also gaining momentum and we members of the ***Global Commission on Drug Policy***[25] are seeing a more common sense approach developing, while being under no allusions of the tough battle ahead.

Drug use and possession remain a criminal offence in over 150 countries worldwide. A 2012 report by ***Harm Reduction International*** documents the 33 countries and territories that retain the death penalty for drug offences, including 13 in which the sentence is mandatory[26]. This violates our human rights conventions and international law. Around 1000 people are executed each year. This criminalisation of drugs has gained its way into national legislation and policies as a consequence of the dominance of the **prohibitionist law enforcement paradigm** in the design and implementation of drug policies. A biased interpretation of international drug conventions is also to blame, as those health diplomats amongst us struggle to work in a world where ***"conventions castrate science".***

The damage that results cannot be underestimated. It has affected millions of lives,

fuelled HIV and hepatitis C epidemics, fed human rights abuses across the globe and subverted the rule of law. For example, following the Arab Spring and the wave of conservatism now sweeping across these countries, drug use, often fabricated, is being used as a handy means to have one's opposition arrested.

To quote the current **Georgian Minister of Corrections, Archil Talakvadze** *"Expecting to solve public health problems by enforcement-led policies can lead to a downward spiral of increased harm and ultimately death. Prisons reinforce lost health, social contacts and broken families. We need to balance active law enforcement with prevention, treatment, rehabilitation and harm reduction while never lowering our commitment to basic principles of human rights".*

At a scientific symposium I organised at ***Euroscience Open Forum 2014 Copenhagen***, Minister Talakvadze left nothing to the imagination for delegates when describing differences between the *'old'* prison system and the changes he is now trying to implement. From 2004 to 2012, Georgia had one of the highest incarceration rates in the world, operating a zero tolerance criminal justice policy. Overcrowding and a failure to update drug regulations and improve prisoner's access to services, as specified by international law, went ignored under the simple logic of placing drug users in a *'drug free zone'.* Yet, thousands became addicted to sedatives and psychotropic drugs widely provided in prisons while many more moved on to new, more damaging substances. The transmission and spread of Hepatitis C got out of control with 42% of all prisoners infected. This contributed to a loss of social contacts and the break-up of families. Thousands of families paid fines and bails for their arrested family members, liquidating their personal wealth and ability to provide for wider family members in the process.

Today, Georgia has embraced harm reduction science and in only a couple of years, is seeing the benefits. Minister Talakvadze has reduced the prison population by 60%. Criminal justice policy has been overhauled and better dialogue initiated between government and civil society. Now, universal access to counselling, testing and treatment of HIV and HCV infections is provided for prisoners.

While on the same panel, **Dr. Andrey Klepikov, Executive Director of the *HIV/Aids Alliance in Ukraine,*** put forward some compelling evidence of how **Russian foreign and trade policy vis-a-vis its neighbours actively seeks through politics, intervention and even annexation to undermine the uptake of harm reduction science.** It ideologically opposes any form of state intervention such as free methadone. He argues that addiction is too profitable a business to let go of with $10 the daily earnings per addicted person. Dr. Klepikov estimates that Ukraine's methadone based treatment programme alone accounted for a loss of $31 million in revenues for the illegal drugs trade in 2013. Following the Russian annexation of Crimea, some 800 patients were cut from methadone treatment programmes with dozens subsequently dying[27].

It sometimes helps to state the obvious. When countries align their drug policies more closely with public health goals, the HIV/Aids among people who inject drugs (PWID) is under control with little if no new infections occurring because of unsafe injection. This is predominantly the case in Western Europe. In countries that maintain harsh penalty-based drug policies, however, the epidemics continue to expand, and the gap emerging

between health-focused and repressive countries keeps increasing. This is predominantly the case in Eastern Europe *(including many new EU member states)* and Central Asia. In fact, Eastern Europe now has the highest HIV growth rates in the world, not Africa. **That is precisely why Ban-ki Moon chose to create the position I now hold as Health Envoy to the region to help spotlight the issues and impact change.**

CRIMINALISATION CAUSES HEALTH-RELATED HARMS

Drug policies significantly impact public health. There is no doubt that drugs may be harmful to health and I in no way wish to be seen to condone drug use. Addiction or *"problematic use"*, which occurs in about 10% of people who use drugs, is certainly a chronic relapsing condition associated with significant challenges for prevention and treatment. However, as reiterated by Minister Talakvadze in his frank account of the Georgian experience above, criminalisation of drugs by law and punitive law enforcement practices equally add to the health burden drug-users face.

Laws and policies have been shown to be critical in influencing HIV and Hepatitis risks among people who inject drugs (PWID). **Over one in five people globally who inject drugs lives with HIV and two thirds are now infected with Hepatitis C.** The figures vary between regions and between countries, from 10 to 80% prevalence of HIV and 40 to 95% prevalence of HCV (the hepatitis C virus) infection among people who inject drugs. The highest rates of HCV infection among PWID are in China, the United States and Russia[28].

Unsafe injection drug use and needle/syringe sharing accounts for one third of HIV infections occurring worldwide (outside sub-Saharan Africa). It also remains the main driver of the HIV epidemic in Eastern Europe and most countries of Asia. Co-infection with HIV and HCV can reach 90% of people who inject drugs in some communities of Eastern Europe and of Asia.

There are several reasons for the high regional incidence and prevalence in Eastern Europe and Asia, most of which relate directly or indirectly to dominantly repressive drug policies:

ACCESS TO SYRINGES IS POOR

Firstly, laws and policies govern access to, and the purchase and possession of syringes. Laws and policies also regulate authorisations for needle exchange programmes (NSP), for substitutive opioid therapy (OST), and for treatment diversion. These programmes are core to the package of interventions identified by the World Health Organisation (WHO), UNAIDS and the UN Office on Drugs & Crime (UNODC)[29] to prevent HIV infection among people who inject drugs.

In combination with the provision of antiretroviral therapy to HIV-positive people who inject drugs who are eligible for treatment, these harm-reducing interventions have

been clearly demonstrated to reduce HIV transmission, decrease mortality, reduce drug dependency, reduce crime and public disorder and improve quality of life.

Put simply, a health-based approach to drug policies must start with the implementation and scaling up of harm reduction. Needle exchange programmes for substitutive opioid therapy can also help reduce the risk of acquiring hepatitis. A further argument in favour is that harm reduction has also been shown to be highly cost-effective.

Yet, despite the scientific evidence for greater efficacy and cost effectiveness, despite the fact that UNODC has clearly stated that harm reduction is consistent with the existing international drug control conventions, and despite the fact that methadone is on the WHO list of essential medicines, restrictive legislation and policies result in substitutive opioid therapy remaining illegal in the Russian Federation. Dr. Andrey Klepikov speculates above as to why this might be the case, but the fact remains that **40% of the 1.8 million people injecting drugs in the Russian Federation are infected with HIV.** Illogical examples abound in the *'West'* too. Access to needle exchange programmes are being restricted in the United States. In a nutshell, needle exchange programmes and substitutive opioid therapies remain the exception rather than the rule, globally.

POLICING IS OFTEN MISGUIDED

Secondly, policing practices have a major, often negative, impact. Over-zealous law enforcement on our streets includes arrests for syringe possession, confiscation of syringes, random/arbitrary urine testing for drugs, and surveillance by police of needle exchange programmes and substitutive opioid therapy sites. This directly influences risk taking behaviours among people who inject drugs. Whereas police may engage suspected drug users in accordance with formal laws, police may also engage, at the community/street level, in practices that are not consistent with laws and policies. Fear of police, arrests and incarceration is a major factor driving people who inject drugs underground to inject in unsafe, unhygienic conditions.

The following are words from a young woman from Eastern Europe quoted in the 2012 report of the *Global Commission on Drug Policy*: *"Fear, fear. This is the very main reason. And not only fear of being caught, but fear that you will be caught and you won't be able to get a fix. So on top of being pressured and robbed (by the police), there is the risk you'll also end up being sick. And that is why you'll use whatever syringe is available right then and there".*

ORGANISED CRIME CONTROLS DRUG ACCESS AND QUALITY

Thirdly, under our prohibitive law enforcement, drug production and clandestine retail are in the hands of organised crime. This logically increases the chances that products are of unknown purity and potency with higher risks. This has been the case for e.g. cocaine cut with levamisole, or else, *'crocodile',* a clandestine *'homemade'* injectable cocktail that has been ravaging drug user communities in Eastern Europe.

MASS INCARCERATIONS MULTIPLY EXPOSURE

Fourthly, punitive laws and policies have led and continue to lead to mass incarcerations. And prisons are not drug-free. A recent study in Ukraine has shown that incarcerated people who inject drugs share syringes with four other users in prison, on average. Furthermore, there are almost no harm reduction programmes inside prisons, not to even dream of needle exchange programmes or substitutive opioid therapies. Inexplicably, this is the case even in several countries that have moved to health-focused drug policies. **In Western Europe, needle exchange programmes are only available in Spain, Switzerland and Germany (1 women's prison)[30] so do not be shy in asking your government why?**

THE RESULT IS DEATH

Finally, restrictive policies increase the risk of death from overdose as people inject in unsafe environments. There are an estimated 20,000 deaths/year from overdose in the U.S and at least one and a half times more in the Russian Federation. Until Minister Talakvadze changed the law recently, people witnessing a possible overdose in Georgia were required, by law, to call the police even before they would call an ambulance. Naloxone, the drug that can immediately stop the effects of overdose and save lives, is far from being universally available as if *"let them die"* is the easier option. We often forget that our drug control regimes have banned the provision of *'legal'* opiates for pain relief for innocent citizens too, as a collateral damage of the *'war on drugs'.* These medications, although on the list of essential medicines, are unavailable in 150 countries worldwide. Ethical questions abound.

At the same time, a large body of evidence has shown that the repressive approach to drug control has failed to reduce the supply and the use of drugs, and that, in settings with aggressive drug control measures, more drugs are now available that are of increased purity, and are available at cheaper retail prices.

HUMAN RIGHTS, HUMAN WRONGS

Punitive approaches to drug policies are severely undermining human rights. This is true of every region of the world. However, here again, the gap is increasing between countries with predominantly repressive or health-focused drug policies.

Repressive prohibition law has led to a dramatic increase in the number of people in detention, in prisons, as pretrial detainees, or people held in administrative detention. As mentioned above, incarceration has been associated with syringe sharing and unprotected sex, and documented as a risk factor for acquiring HIV infection in countries in Western Europe, Canada, Brazil, Russia, Iran and Thailand. In the U.S, where ethnic minorities are much more likely to be incarcerated for drug offences than whites, prison has been identified as a key factor for the markedly elevated HIV infection rates among African Americans.

Some countries maintain compulsory drug detention programmes where evidence-

based treatment of addiction is absent. In China and South East Asia, an estimated 235,000 people are held in such centers. Just to remind you, around 1000 people are executed each year.

At the community level, there are many examples of policing practices, beyond and often against the law, that have imposed abusive punishments on people using drugs, and particularly women, young people and ethnic minorities. Allow me to share with you one example of evidence given by Elana, a young woman from Poltava, Ukraine as part of the Eurasian Harm Reduction Network's submission to the UN Special Rapporteur on violence against women (October 2012).

"I will never forget one incident that happened in December 2010. We were standing as always near the belt line road, it was freezing and getting dark. A minibus drove up to us. Several policemen from the Special Designation Police Department wearing uniforms grabbed me and the other three girls and pushed us into the minibus. They drove us to the suburbs, stopped by a lake, and despite it being very cold they ordered us to take off all our clothes. Then they poured gas over a pile of our clothes and burnt them. They forced us into oral sex with each of them and then with burning torches they started pushing us into the freezing lake. Then they left and we had to get back to the city with no clothes on. After this incident one of us had pneumonia and died, another girl's feet was frost-bitten and was amputated. I stayed in the hospital with pleuritis that progressed into tuberculosis".

SOCIAL VIOLENCE

Social violence comes as a third area where the gap is increasing between countries with a repressive focus and those that have opted for policies prioritising health and human rights. Countries that have been fighting the *'war on drugs'* in Latin and Central America have seen a major wave of violence, corruption and instability. At least 60,000 violent deaths are estimated to have occurred in Mexico, for example, in the last ten years since the war on drugs was scaled up.

The gaps mentioned above keep widening in all regions. As the world now prepares for a special session of the UN General Assembly on drugs in 2016, it is time that the consequences of criminalising drugs are acknowledged by the international community. And it is also time for the international community to consider shifting drug policies towards decriminalisation of drug use and possession.

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Alcohol
3.3 million deaths annually - WHO

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ALCOHOL: WHY EVIDENCE-BASED POLICIES ARE OFTEN THE EXCEPTION RATHER THAN THE RULE

The validity of the European Union in the eyes of its citizens is that it can provide effective and useful public policies. Good policies are always based on good evidence, on good science. However, much weak or biased research is now presented as fact to policy-makers, especially in the area of lifestyle sciences. Europe desperately needs an arbiter of good science and a re-think of how its in-house science service, the Joint Research Centre, might best provide this. Unlike the US Federal Drug Administration (FDA) or the National Institute for Care Excellence (NICE) in the UK, Europe currently has too patchy an approach to tackling issues around substance use. Amongst the EU research centres, institutes and agencies that have developed since the food crises of the 1980's and 1990's, there is too little expertise at-hand on substance addictions. With the abolition of the Office of Chief Scientific Advisor who will fill that role? Industry, academia and wider society should be concerned.

Harm caused by alcohol abuse is found in every European country. The latest WHO report sets a figure of 3.3. million alcohol-related deaths per annum. Problems and diseases related to the harmful use of alcohol are high on the agenda of global public health policy, as they equally drive the corporate social responsibilities of beverage producers. Underage drinking, binge drinking, drink-driving, illness and disorder: all are reported regularly in the media, in health reports, in statistics and in reality. These are serious issues that deserve serious responses.

Without detailing the too obvious to mention, it is, nevertheless, worth noting that consumption of moderate amounts of alcohol can bring health benefits, some advantages in employment, enjoyment of life, cuisine, culture, etc. And taxes raised from the consumption of alcoholic beverages contribute towards the funding of many public services – including health.

As such, the issue of how to address alcohol-related harm is not straightforward, and 'science' is used on all sides of the argument to support particular points of view. Some of the research is contradictory, some of it is unconvincing, and some appears to be shaped from the outset with a particular policy objective in mind.

In *SciCom's* last compendium titled ***"addictions & their brain reward systems"***

referenced in the preface, there was a strong focus on ***"drinking patterns, culture and policy responses"*** from a global perspective taken by Dr. Marjana Martinic of the *International Alliance for Responsible Drinking* (IARD)[31]. Similarly, alcohol treatment expert Andy Stonard of *Esprit du Bois* and Professor Philippe de Witte, Head of Behavioural Biology at the *Université Catholique de Louvain* (UCL) give a lot of food for thought about the science of alcohol and young people. Both are worth reading in conjunction with my piece which takes a closer look at the best practices and pitfalls we encounter as industry when trying to feed in scientific evidence to EU policy-makers, amongst others.

Policy-making should be based on robust science and research. Everybody will claim theirs is the best. Where stakeholders differ is how that *'robustness'* might be measured.

Take these statements:

"Europeans drink more alcohol than anyone else in the world."
"European consumers drink less than consumers in both Africa & South East Asia."

If you are an **advocate for temperance** and you would like European policy-makers to impose greater restrictions on the alcohol beverage sector, then you are likely to claim the first statement above and cite countless statistics about the harms caused. Claiming that Europeans drink more than anyone else will strengthen your case as in itself, it appears *'wrong'* to be top of any substance use league table.

If you **represent the alcohol sector,** on the other hand, and believe there are more than enough restrictions on how those products are marketed and sold, then you will prefer the second of these statements, when meeting members of the European Parliament, governments, and so on. You might also further clarify that European consumption stems from legal sources i.e. quality controlled whereas up to 85% in certain countries is uncontrolled *'home brew'.* But that's splitting hairs.

So, which of these statements is true? Well… both in fact, depending on what you understand by *'average consumption'.* It should be a simple calculation: take the total amount of alcohol consumed in a region, and divide it by the number of people in that region. But which *'people'?* Should you include everyone in that denominator – including new born babies, 2 year olds, 3 year olds, etc., or should you include only those who fall within the usual drinking ages?

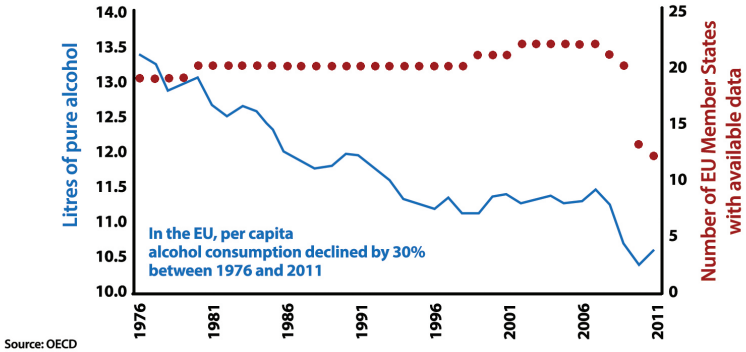
If you include all people aged 15+ in the calculation, you will find Europeans drink more than anyone else. However, if you only take into account those who actually drink *(the drinking population)*, then you find that European consumers drink less than those other regions. This is not only the result of demographic differences *(including other features than age, namely income, religion, etc.)*, but also the number of people who actually consume alcoholic drinks or abstain from drinking. My message here is that facts are easily misunderstood.

Does it matter? Of course it does. Figures like these are used every day by non-governmental organisations, health advocates, industry experts and policy-makers

in countless meetings and fora. They feature in press releases and speeches. They are quoted as if they are incontestable. The objective is to have a sufficient number of media and other influencers take for granted the *'spin'* desired: *"Europeans Drink Most!"* becomes the headline, then repeated indefinitely in future journals, speeches and blogs. The original calculation or research behind the headline has served its purpose. Alternative interpretations of the research are derided as being defensive or out of touch.

The fact that according to the OECD's research below, **consumption of alcohol in Europe has decreased significantly over the past 30 years,** and seems to be relatively constant during the last 10 years or so, is not a fact that the temperance movement will highlight. On the other hand, industry does think it highly relevant.

PER CAPITA ALCOHOL CONSUMPTION (IN LPA) SINCE 1976



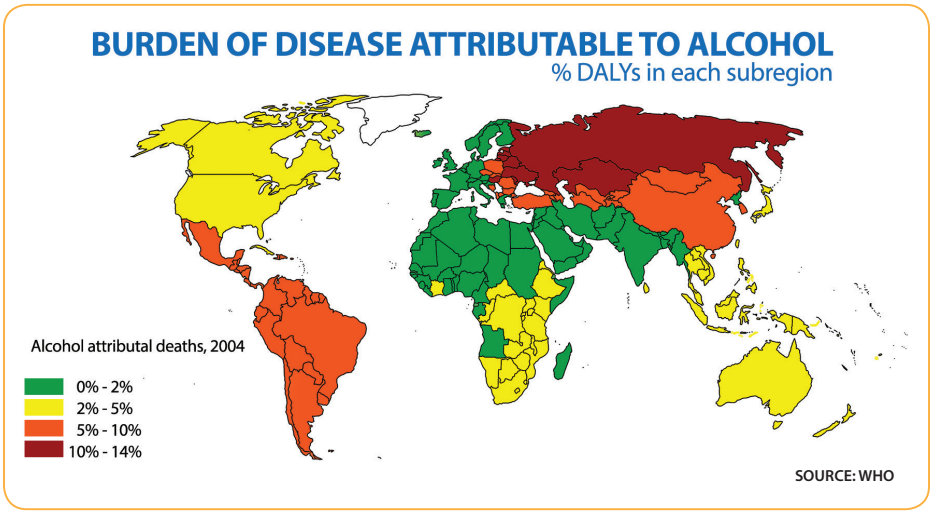
Source: OECD

Moreover, NGOs and related scientists draw a direct line between *'Europe is by far the world's heaviest-drinking region'* [32] and the level of alcohol related harm, e.g. the *'European Region remains the area of the world with the highest levels of alcohol consumption and alcohol related harm.'* [33] However, the map chart below *(also published by WHO)* shows a different picture as regards the regional distribution of alcohol attributable deaths in 2004.

THE ETHICS OF EU INSTITUTIONS GENERATING THEIR OWN SPIN

As a centre for policy-making, Brussels attracts more than its fair share of spin. For every policy issue under discussion in the European Parliament, lobbyists – both corporate and not-for-profit – will seek to communicate their particular take on science to MEPs and their assistants. Activists will find the piece of research that supports their particular policy objectives and promote that research as the only truth. **Facts become weaponised. The subtleties and weaknesses of much of the original research will be ignored or lost.**

But the European institutions also contribute to the spin. Policy-makers' speeches and questions will cherry-pick aspects of previously published research to



poke holes in, or support, particular legislative initiatives. My point is that European Commission documents will quote some scientific findings and not others, depending on the proposal a particular Commissioner wants to make. Commissioners may even contradict each other with the same research. Robust scientific reports on the Joint Research Centre's website will be put up or taken down as the cause necessitates. And some go further, by offering grants for research, the direction of which the European Commission dictates, but the robustness of which sometimes leaves much to be desired.

In alcohol research, we have witnessed the bulk of Commission funding go to the same researchers in broadly the same policy areas over the past 5 to 6 years. While some of that research appears to have been well executed and reasonably neutral in its outlook, many projects seem to be aimed at particular policy conclusions from the outset, and the research developed in a way to justify those policy recommendations.

When the European Commission funds research, does it have any responsibility over the quality of that research? I would argue that it does. Typically, results are published on the Commission's own website[34], even if the reports themselves will always contain some disclaimer as to the ownership of the work. In such instances, there is a need for a **right of rebuttal**, or for **counter-arguments to be posted** alongside the original research. Otherwise, it has all the appearances of being sanctioned by the European Commission.

MY CALL FOR ACTION HERE IS THAT:

a) The allocation of public health programme funding should be based on a sound methodology in line with international or European professional diligence standards applicable, for example, to market research. The European Commission

then has a responsibility to ensure that the research that is conducted and finally published *(with acknowledgements to the EU funding)* is of sufficiently high quality.

b) Research presented to inform the public EU debate should respect principles of good research. Research which deviates from those principles should be clearly identified *(and when necessary, named and shamed)* – not least by the organisation that commissioned the research in the first place. Conversely, if research follows the required standards, it should be welcomed by all stakeholders, regardless of its origin/funding.

THE COMPLEXITY OF SETTING THE RIGHT ALCOHOL POLICIES...

ALCOHOL CONSUMPTION IS PROVEN TO HAVE HEALTH BENEFITS TOO

For those who would favour severe restrictions in the availability of alcoholic drinks, who would favour increased taxes so as to force up prices, the simple message to policy makers is *"consumption of alcohol is bad, so cut consumption and harms will disappear."*

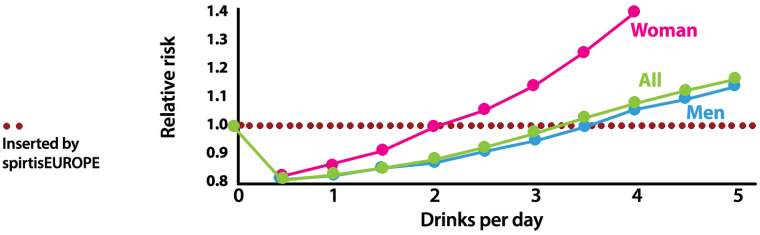
Regardless of the many profound ethical arguments about *'nanny state'* interventions raised by Professor Kinderlerer, Professor Kazatchkine and others in this publication, what upsets this simplistic narrative is the fact that numerous studies show that otherwise **healthy adults who consume alcohol in moderation may face a lower risk for a number of conditions,** in particular age related risks such as coronary heart disease, ischemic stroke, diabetes and dementia. My point is not to argue that *"alcohol is good for you"* in an irresponsible manner and as the representative of an alcoholic beverage sector association, but to point out that there are black and white scientific evidences that must be factored in.

Drinking patterns are of great relevance: moderate drinking, compared to heavy drinking, and, for that matter, to not drinking at all, has been shown to be associated with certain beneficial health effects.

According to a 2006 meta-analysis *'consumption of alcohol, up to 4 drinks per day in men and 2 drinks per day in women, was inversely associated with total mortality, maximum protection being 18% in women […] and 17% in men. […] Our findings, while confirming the hazards of excess drinking, indicate potential windows of alcohol intake that may confer a net beneficial effect of moderate drinking, at least in terms of survival.'* [35]

A number of independent studies also show that moderate drinkers generally enjoy not only a reduced all-cause mortality risk but also may benefit psychologically, e.g. feelings of pleasure, happiness or stress relief.[36] Chan concludes *'regular alcohol consumption is associated with increased quality of life in older men and women.'*[37] Or Goldberg[38] who found that *'compared with abstainers, moderate drinkers exhibit improved mental status characterised by decreased stress and depression, lower absenteeism from work, and decreased incidence of dementia (including Alzheimer's disease)'* Or more recently, Valencia concluded: *'Alcohol drinkers, including those with heavy drinking, reported better physical HRQL [health related quality of life] than non-drinkers.'*[39]

RELATIVE ALL-CAUSE MORTALITY RISK: PEOPLE CONSUMING 1 TO 4 ALCOHOLIC DRINKS / DAY COMPARED WITH ABSTAINERS



Source: Di Castelnuovo et al 2006 (p. 2442)

WE MUST RE-DEFINE GOOD *VERSUS* BAD RESEARCH

As all contributors are at pains to point out in this *SciCom* series, the dialogue between science and policy is *never* straight-forward. The fact is, bias is introduced in a number of different ways, not least by ideological positions and agendas aimed at particular policy outcomes. New Zealand Chief Science Adviser, Sir Peter Gluckman, demonstrates clearly in his recent health case-studies how policy-makers have countless sources of solicited and unsolicited advice. Thus, science can rarely speak with one voice. Yet, surely we must be able to agree some basic ground rules that *'good'* research is *'good'* no matter who funds it, provided it is grounded in certain principles, generating reputable, credible and reproducible findings that derive from sound scientific methods, and using reasonable and fair assumptions and verifiable, correct data inputs? But what constitutes *'good'* research? We suggest the following five principles as a start:

1. RELEVANCE

- There will never be enough funding – nor enough researchers – available to undertake all possible research. Whatever resources are available must be optimised: focusing the correct resources on the most relevant and pressing needs.

2. NEUTRALITY AND OBJECTIVITY

- As noted above, industry questions the objectivity of activist researchers as it appears that some research projects are used merely as a means to support pre-decided policy approaches. At the same time, NGOs clearly question and challenge industry involvement in research. Policy-makers too can express this bias by declaring an *'everybody's science is welcome approach'* but then ultimately paying lip-service to it. The citizen is the loser here.
- We believe good research is conducted by experts in the particular field of research, rather than by advocates with a pre-existing policy viewpoint.

- Policy-makers should consult more widely. Industry contributions should be given the same level of attention as academic contributions and evaluated according to the same criteria as NGO contributions.

3. FAIRNESS AND TRANSPARENCY

- **In the allocation of funding:** The process of applying for EU funding seems convoluted and complicated enough to become almost a full-time job, which may explain why the same activist researchers appear to get funded time and time again. Recent efforts to cut red-tape are welcome, but will not resolve the issue of industry science being de-facto disadvantaged in entering the race.
- **In the methodology used in the research:** Before the research starts, some consultation with those stakeholders likely to be most affected by the research would be useful, allowing researchers to avoid potential problems with their proposed methodology.
- **In the manner in which the conclusions are presented:** Frequently, research funded by the European Commission is also accompanied by recommendations for public policy changes. Researchers/authors should be required to disclose their associations not only with business, but also with any policy advocacy groups *(for example, temperance groups, health lobbies, etc.)*. A good start would be to have all 'advisers/experts/reviewers/funding allocators' to DG Research & Innovation and its family of sister agencies complete the new Transparency Register.
- **In allowing the right to reply:** All stakeholders should be provided with a right of reply – allowing the *(industry, or other)* response to be published next to the original research on the European Commission website. A more visible *'Science Ombudsman'* would also add value to Horizon 2020.

4. ROBUSTNESS

- Those involved must respect principles of good research and work in accordance with the accepted standards of the discipline. Benchmarking excellence while rooting out mediocrity should be a greater priority and not just funding for the sake of funding to get the money spent.
- Data sources should be transparent and accessible.
- There should be unbiased geographical coverage / broad baseline if results are extrapolated to inform EU policy. The research must also ensure the whole spectrum of credible research is reviewed and taken into account.
- Published research is generally of higher standard than that which remains unpublished. However, if peer review is the best system that we have, it is not the panacea if the *'peers'* share the same bias as the author.

5. ENGAGEMENT

- Consultation with, and participation of, all interested parties during the process is a must. It is a no-brainer that policy-making that involves all stakeholders stands a better chance of success, take-up and consumer acceptability. Policy-makers must also be

receptive to scientific advice, even when this advice is uncomfortable. Finally, we are talking about tax-payers' hard earned cash here, so policy-makers must do more, in tandem with industry, to challenge *'science'* to deliver on their public investment.

WHY INDUSTRY, ACADEMIA & SOCIETY SHOULD WORRY

Alcohol-related harm is a serious and a complex issue. There is no escaping that. Policy-makers who look to set the appropriate policies to address that harm deserve all the support and help that we, and other stakeholders, can give them. We can learn a lot from those national strategies that have taken up harm reduction science and a more health-focused approach above the reflex for a short-sighted, repressive reaction as Professor Kazatchkine espouses above.

We live in a Europe anchored by the principle of a Common Market that brings endless benefits, no question, but necessitates a permanent, creative tension between 28 largely homogeneous, but still very different systems that when it comes to alcohol, have clearly different consumption patterns, cultures, traditions and policy-responses. As our ***Consultation Event*** participant, Professor Klaus Bock, *Member of the European Research Council, Euroscience Open Forum 2014 Copenhagen Champion* and former *Executive Vice-President for Research at Carlsberg* explained, *"you can do what you like with restrictive alcohol policies in Denmark but people will simply cross the border to Germany or elsewhere".*

Similarly, adapting a one-size fits all approach from Brussels might look good on paper but is hardly going to work in practice if not well thought through. This requires serious scientific engagement at all levels. If policy-makers from the European Commission, Parliament or Council do not heed Sir Peter Gluckman's advice that you need to start out with an open mind, get the right people around the table, gather the right evidence and then think about the right policy, then things are doomed to fail before they start.

Above all, our policy-makers deserve to be briefed in a fair and honest manner. They deserve to receive the best available research, whether that comes from activist scientists, or has been funded by industry. As I try to explain in a back-to-basics plea above, good research is good, no matter its source. Bad research should be called out. But who will do that?

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Tobacco
6 million deaths annually - WHO

Ms. Deborah Arnott (UK), GUEST CONTRIBUTOR, MBA FRCP (Hon), Chief Executive, Action on Smoking & Health (ASH UK) is a well-respected public health campaigner championing greater awareness about the tobacco epidemic worldwide, while pressing for evidence-based policy measures that do not attack smokers or condemn smoking. Reporting to the Royal College of Physicians, ASH provides the secretariat for the UK's All Party Parliamentary Group on Smoking and Health. ***URL: www.ash.org.uk*** ***Email: deborah.arnott@ash.org.uk***

TOBACCO: NOVEL PRODUCTS CHALLENGING OLD ETHICAL STANCES

The UK and USA are home to the leading tobacco transnationals and the birthplace of the twentieth century tobacco epidemic. Around mid-century, smoking peaked in the UK with around 80% of men and half of women smoking, slightly higher than the US[40] at its height. This was an epidemic caused by manufactured cigarettes, consumption of which increased over 100 times during the century. Six million[41] people a year now die globally from tobacco smoke, mostly smokers but including over half a million people killed by second-hand smoke. Unless action is taken the tally is expected to grow to eight million a year by 2030 and by then over 80% of these deaths will be in low and middle income countries. These countries are increasingly suffering from diseases caused by smoking such as cancer, diabetes, cardiovascular disorders and chronic respiratory illnesses. **Tobacco caused 100 million deaths in the 20th century. If current trends continue, it may cause one billion deaths in the 21st century.**

To answer the question posed by Professor Kinderlerer on the ethics of intervening in the lives of addicted people, yes of course human dignity and freedom are fundamental principles. However, to quote John Stuart Mill from On Liberty, *"The principle of freedom cannot require that he should be free not to be free."* Mill was referring to slavery, but addiction, particularly to a substance as deadly and addictive as tobacco, is also a choice which limits rather than enhances freedom. In the UK two thirds of smokers want to quit[42], many more wish that they had never started, yet **long-term success rates in quitting are well below one in ten.** It is hardly surprising that there is strong popular support for the rule of law to be used to limit smoking, support which has been growing in recent years rather than declining.

The public, certainly in the UK, understand that policy-makers, have an ethical responsibility to put in place policies designed to drive down smoking. I would add that **policy-makers in the UK and the US, home of the tobacco transnationals, also have a responsibility to help prevent the global epidemic taking root in low and middle income countries.** That was one of the driving forces[43] behind the development and implementation of the *WHO Framework Convention on Tobacco Control*. The world's first health treaty, it contains a comprehensive set of measures designed to drive down consumption of tobacco by reducing both demand and supply.

In a spare moment during the final negotiations on the *WHO Framework Convention on Tobacco Control,* I visited the Red Cross museum in Geneva. On the wall was an old

banner setting out the rights of prisoners of war in the early part of the twentieth century. I was astonished to see that the right to tobacco was set alongside the basic human right to food and water and given equivalent weight. This illustrates how the balance between the rights, and responsibilities, of smokers and non-smokers has evolved and they are continuing to evolve.

Not much more than twenty years ago when I was heavily pregnant the rights of smokers still had priority. Smokers would light up in front of me at work without even bothering to ask if I minded. Despite the fact it made me feel sick and I knew that cigarette smoke was harmful, I had no right to request, however politely, that they stop. Subsequently I worked with the company doctor and we held a ballot of all employees on whether they wanted smoking on the premises to be prohibited or not. The trade unions in our heavily unionised workplace didn't object to our ballot, despite almost all of their representatives being heavy smokers, because they didn't for a minute believe we'd win the vote. But we did, and by an overwhelming majority. Non-smokers who had felt unable to speak up individually, when given the opportunity as a group, made very clear that they didn't want to be exposed to tobacco smoke.

Years later in 2003, I was recruited by ASH (UK) to campaign for laws to require smokefree enclosed public places and by 2007, the UK had implemented comprehensive smokefree laws, following in the footsteps of Ireland, New Zealand and many parts of the US. The same year the *WHO Framework Convention on Tobacco Control Conference of the Parties* had adopted comprehensive guidelines very much along the same lines. In retrospect it looks easy, the laws are widely accepted and non-controversial. But it was not. We had to fight to gain acceptance for the idea that protection from second-hand smoke in enclosed public places should be made mandatory and not left to voluntary action by organisations and employers.

Just after the millennium half of all workplaces were smokefree in the UK, but this was biased towards larger organisations and professional and managerial workforces. **The majority of low paid routine and manual workers still had to suffer smoking at work, and because rates of smoking were higher in those groups they were exposed to more smoke.**

In the UK we had great difficulty persuading the English government that they should legislate. ASH (UK) was set up by the *Royal College of Physicians* to be an evidence-based advocacy organisation working to reduce the harm caused by tobacco. Together with all the other leading health organisations we provided extensive evidence of the harm caused by second-hand smoke, but the evidence was not sufficient. It was not that the politicians did not believe the evidence that second-hand smoke was harmful, that they accepted, but as the Health Minister's political adviser said to me *"show me the votes".*

The legislation passed because we were able to do just that. Indeed over the period May 2004 to December 2005, support for smokefree legislation, including all hospitality venues, rose from one half to two thirds of the adult population[44]. Support grew because the public were engaged in a debate, through a government consultation and in the media, about the rights of smokers versus the rights of everyone else. The debate hinged

on John Stuart Mill's harm principle, as elaborated in On Liberty, that, *"The only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others."* The harm principle was cited widely on both sides of the argument for and against smokefree laws, because it is a widely accepted benchmark in the UK, as in many other democracies, for whether or not government action is acceptable or not. The argument was won in particular because the **public accepted that the rights of workers in the hospitality industry to be protected from second-hand smoke superseded the rights of smokers to smoke wherever they wanted**. It was the same case in Ireland when the first public-place smoking ban was introduced in 2004.

POSITIVE STEPS MADE, BUT A BATTLE NOT YET WON

I was reminded recently that this argument is still to be won in many parts of the world. On a trip to Sarajevo, in Bosnia Herzegovina, it seemed as though every restaurant I visited allowed smoking, with at best a cursory and ill observed no smoking section. In one I even saw the chef behind the counter, smoking, while cooking. I came home every night smelling of tobacco smoke, an unpleasant and unusual experience. As a little British boy too young to remember what it used to be like said to his mother, *"Why are these people being allowed to smoke over me?"*

However, ASH is not anti-smoker, we're anti-smoking. That is a very important distinction. While I have no desire to go back to the days when smokers' rights were the priority I do believe there should be a balancing of rights and responsibilities, not just of smokers but of non-smokers, and not just in the home of the tobacco epidemic, but globally. Nowadays I fear that there is a **danger that smokers' rights are not sufficiently taken into account,** particularly when it comes to the regulation of less harmful products than smoked tobacco such as electronic cigarettes. Country after country, from Canada to South Africa to New Zealand, with murmurs in France and Germany, are banning these products or regulating them as strictly as tobacco products as if they were as dangerous as smoking. This is not based on sound scientific evidence which is proving the contrary, but fear of the unknown and a residual desire to punish the smoker/vaper.

It is not easy determining an appropriate regulatory framework for less harmful products when the evidence base is still evolving. I have been criticised both for supporting a regulatory framework which is too stringent and one that is insufficiently strict. I have been attacked for challenging the presumption of *'at least do no harm'* and for not adhering to the precautionary principle. But **the precautionary principle is often misquoted** as providing substantive prescriptive guidance on what steps regulators should take, rather than, as is generally accepted, that a lack of decisive evidence of harm should not be grounds for refusing to regulate. Regulation of electronic cigarettes should be designed to maximise the benefits while minimising the risks. Policy makers need to take into account benefits and risks of all kinds both to current users and potential users amongst smokers and ex-smokers, but also to non-users and never smokers, in particular amongst children and young people.

Those who argue in favour of more stringent regulation of electronic cigarettes have a

range of concerns about unintended consequences.

They are concerned that:

- **e-cigarettes might be a gateway into smoking;**
- **that their use in places where smoking is forbidden might renormalise smoking;**
- **that dual use by smokers might sustain addiction rather than help quitting;**
- **that the long-term health effects are unknown;**
- **that second-hand vapour may be harmful; &**
- **that tobacco companies may use them to subvert controls on tobacco industry involvement in policy development & circumvent laws to prevent tobacco ads.**

These are all rational hypotheses about potential harms, but the overwhelming evidence to date is actually to the contrary: that **these products have provided public health benefit,** certainly in the UK where we are a leading monitor engaged with smokers and vapers.

THE UK: DEVELOPING THE EVIDENCE BASE

In the UK, rapid growth in e-cigarette use has been associated with increased rates in adult quitting and a continued decline in adult smoking prevalence, now below 20% for the first time since records began.[45] **Research by ASH over the last five years has now been supplemented by official government statistics finds that almost no-one who is not a smoker is using electronic cigarettes.**[46, 47] The most common reasons cited by smokers for using e-cigarettes is to help them quit smoking, prevent relapse or cut down and that being able to save money by switching is a powerful motivator. Smokers are increasingly using electronic cigarettes to help in quit attempts and they are **proving significantly more effective than medicinal nicotine products bought over the counter such as patches, gums and sprays.**[49]

There is **little sign of youth use** except amongst pre-existing smokers.[47, 48] The vast majority of young people who have not smoked or vaped have no intention to do so. Youth and adult smoking prevalence has continued to decline, not something you would expect to see if e-cigarettes were a gateway into smoking.[50] While a causal relationship cannot easily be proven, there is certainly **no evidence that the growth in e-cigarette use is leading to an increase in smoking.** The evidence from the US is very similar.[51]

Smoking cigarettes can never be made safe, inhalation of smoke, whether from cigarettes, household fires[52], or any other source is harmful, the lungs are a fragile organ. It is too soon to say how safe e-cigarette use is longer-term and more research is needed. However, although the precise extent of harm from long-term use is not known, from the concentrations of potentially harmful inhalants in vapour, e-cigarette use from brands that have been tested so far is likely to be **many magnitudes safer than smoking tobacco cigarettes in terms of long-term health risks.** The vapour exhaled by e-cigarette users contains concentrations of chemicals which are below concentrations expected to cause significant harm to health of bystanders.

We at ASH are not against regulation and we would like to make sure that the risks, in particular of youth uptake, are monitored and action is taken if they materialise, as appropriate.

That is why we support **an age of sale for e-cigarettes of 18** with appropriate enforcement. We support regulation to **prevent marketing promoting smoking** and encouraging uptake by non-smokers and young people. We also want to see appropriate regulation to ensure that **e-cigarettes are safe, reliable and effective and that their marketing is controlled, and aimed at smokers.**

In Europe, we have an evolving twin track regulatory approach which will be in force by 2016/17 which will require novel nicotine delivery devices to be regulated under the **EU Tobacco Products Directive**[54] or to have a medicines licence.

There are those concerned that such regulation is already too stringent and may undermine the growing market for alternative nicotine products. Our view is that since this is the regulatory framework that is due to be put in place we need to do all we can to ensure that it works to the benefit of smokers and of public health, in line with the evidence base.

ASH has supported medicines regulation and is pleased to see the UK medicines regulator the **MHRA *(Medicines and Healthcare Products Regulatory Agency)* has given a licence to the first novel nicotine product, a nicotine inhaler and is in the process of licensing the first electronic cigarette.**

But even this has its problems. The first licensed product is being marketed by a company which is a wholly owned subsidiary of British American Tobacco, which could mean that for the first time a tobacco company product will be available on prescription. This is causing concern amongst many in the public health community who find it hard to believe the tobacco industry is acting in the public interest. It is our view that products, whoever they are made by, should be prescribed on the basis of clinical need in the light of the evidence base. However, it is essential, in line with Article 5.3 of the WHO FCTC, that this does not allow BAT, or any other tobacco company for that matter, a foot in the door to unduly influence tobacco policy.

Having grown rapidly for a number of years, recently electronic cigarette use has started to flat-line in the UK. In these circumstances the mantra *'at least do no harm'* needs to be re-examined. WHO produced a reasonably nuanced policy report in advance of the *2014 Conference of the Parties to the WHO Framework Convention on Tobacco Control,* which stated that ecigrettes *"represent an evolving frontier, filled with promise and threat for tobacco control."* [53] However, its tweets were much less nuanced, for example stating that the *"WHO report shows: e-cigarettes & other electronic nicotine delivery devices pose threats to public health".*

Alarmist statements about the risks of vaping by health professionals who should know better are leading to newspaper headlines like *"I thought my e-cigarette was a miracle. Turns out, I was smoking the equivalent of 40-a-day".*[55] And ASH research shows that although the majority of the public still realise that vaping is less harmful than smoking, the proportion thinking it's just as or more harmful doubled between 2013 and 2014 from 7% to 15%. The public have a right to accurate information and nicotine addicts have a right to access to safer nicotine products than smoked tobacco.

Why is this of concern? Because over fifty years after Richard Doll's seminal research

providing convincing evidence that smoking caused lung cancer was first published in the *British Medical Journal*, smoking is still an epidemic. Nearly one in five adults in the UK smoke and 100,000 die prematurely each year from doing so. Amongst the most disadvantaged in society, those with mental health problems, living in poverty, or lacking education, smoking rates are much higher. Smoking rates are declining but at a pace which means that for decades to come smoking will remain the major preventable cause of premature death. That is in a country which has had a comprehensive strategy in line with the recommendations set out in the WHO FCTC for many years. In many other countries without such strategies in place rates of decline are smaller or non-existent. We should be worried. That is not to say that we should stop doing what we are doing, traditional tobacco control policies are effective, but they are not sufficient.

OVER-REGULATION COULD BE COUNTER PRODUCTIVE

Electronic cigarettes have not so far been the solution for all smokers, but they are already, early on in the product life cycle, having a significant impact. Our research shows that only one in three smokers who take up electronic cigarettes switch completely, the remainder continue to smoke as well. If the products are improved so that more smokers who find it impossible to quit are encouraged to switch completely to electronic cigarettes, the potential health benefits would be much greater.

In such circumstances over-regulation itself may be the very harm that we need to avoid. It could lead to smokers continuing to smoke who otherwise would switch to safer products. Banning or heavily regulating electronic cigarettes in the same way as tobacco products, or even just discouraging their use does not equate to *"do no harm"*. Policy makers need to take note of Sir Richard Peto, who concluded that ***"helping large numbers of young people not to become smokers could avoid hundreds of millions of tobacco-related deaths in the middle and second half of the twenty-first century, but not before. In contrast, widely practicable ways of helping large numbers of adult smokers to quit… might avoid one or two hundred million tobacco-related deaths in the first half of this century."***

We must not forget that electronic cigarettes are potentially one of those widely practicable methods of helping adults to quit. When it comes to tackling our greatest preventable killer, we must insist on nothing less than ***'evidence-based policy'*** trumping ***'policy-biased evidence'.***

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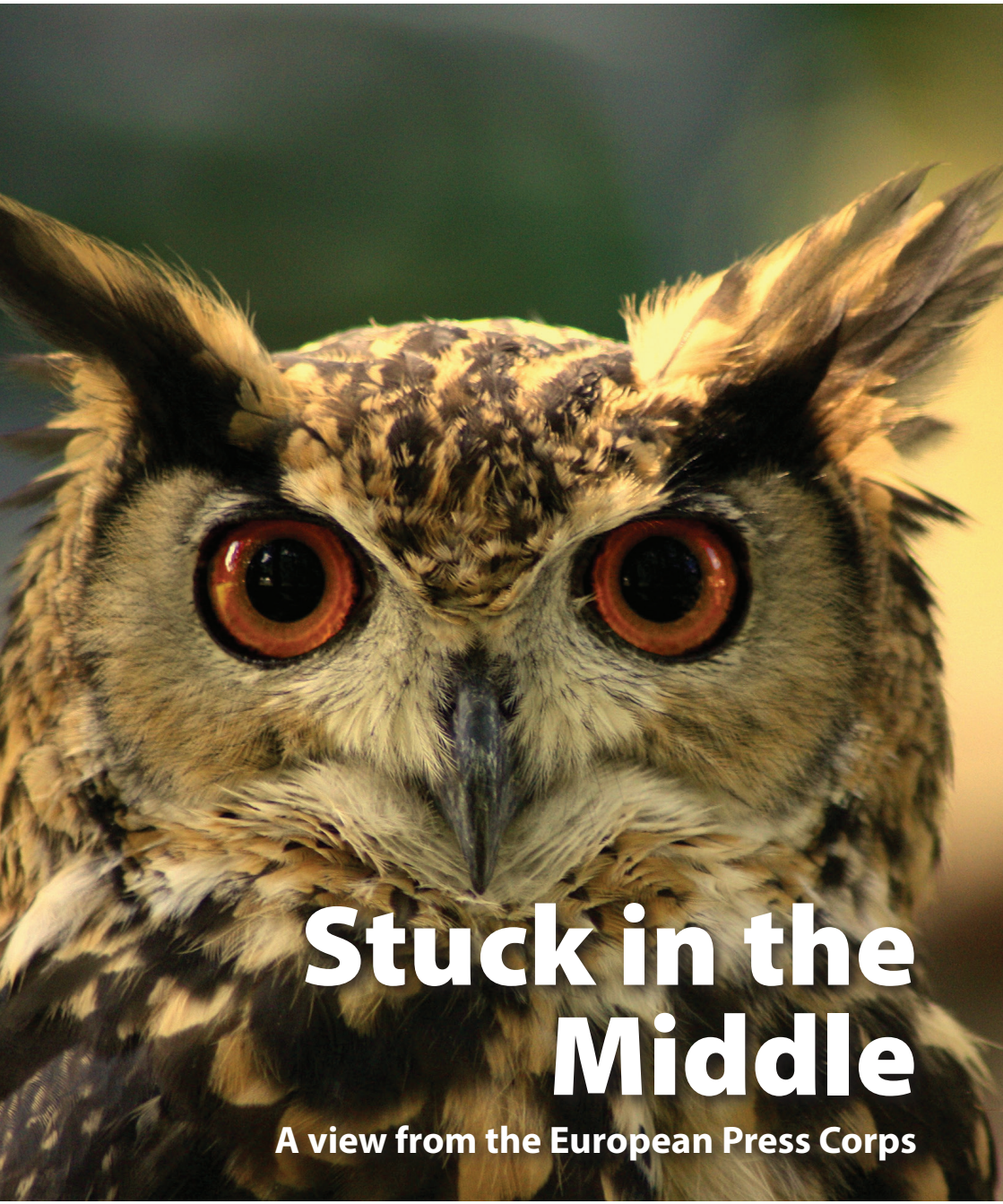

Stuck in the Middle

A view from the European Press Corps

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A VIEW FROM THE EUROPEAN PRESS CORPS

Generally, journalists are stuck in the middle, caught in a tsunami of information coming from all sources. It has become a lot more complex in recent years. Once people get hold of your contact details in Brussels, the bombardment never stops. There are briefings and counter-briefings, tip-offs and been frozen out, one-to-ones and press trips, and dozens of daily press releases and reports to try to decipher if you are interested. It might be a tad simplistic, but certainly when I started out the world of journalism was divided into two kinds of stories — those citizens needed to know to play their role in the democratic process, and those that were merely intended to entertain.

That world has passed. The goal-posts have been changed in the old competition to make the important interesting and the interesting important. **It is about persuasion rather than informing.** Now citizens are children in a sweetie shop choosing their favourite sweets and the media competes to provide whatever they wish.

The filters journalists once used to choose which stories to concentrate on have been breached and now go far beyond the old fashioned idea of *'news value'.*

Skilled media and public relations officials armed with the results of focus groups and psychologists pick the choicest piece of information, flesh it out to ensure it forms a cohesive whole, trot out a selection of supporting facts and figures and send it out, oven-ready, to the news *'operative'* in the media.

Fashion and fads dictate more than ever before what is newsworthy, with vested interests using all the machinery at their disposal to ensure that their judgement is the one that becomes the accepted, common-sense one. **Their view, their product, their service becomes the answer to whatever question, whatever problem is posed.**

For this is not just a game of who can get the most media exposure. The media is just one facet for the players. The Chinese-wall between lobbying and public relations in professional companies is less than paper thin — something clearly evident in centres of power such as capital cities, Brussels and Washington.

With consultations, advisory groups, expert committees, representative associations, business bodies, non-governmental organisations, supporting consumer groups, exhibitions, conferences, debates, prizes and awards now all part of the political decision making process, the media as well as the politicians and public are part of the target audience to achieve a very specific end.

Tasty little stories, expert analysis on demand and prestigious advocates-for-hire willing to provide op-ed pieces for willing media, it can be game, set and match for the most skilful, and wealthy, interest. Science is frequently included in the weaponry of advocates and opponents. Once seen as objective by citizens wooed by its magic, with each piece of research having an automatic QED attached in people's minds, it too has become just another armament in the game.

Now scientists are trotted out, lances in hand like Medieval knights to battle face-to-face as part of the backdrop to creating the perception that all is well, and the solution is to hand. They are asked to present the definitive answer to what are frequently in effect cultural questions, or issues that should be a matter of personal choice. These issues are difficult in themselves for any government to rule on, and so offer a fertile space for professionals to use their skills and offer neat answers.

On the one hand, if an action, a service, a product is causing the economy harm, a government could be justified in taking action. On the other hand, any action the State takes may in the end be seen as creating alternative problems as Deborah Arnott suggests, little wonder regulation is a mess.

The civil servants involved in the process have to manage the politics and we have some examples of how this can appear to leave the bureaucrats relying on Machiavellian action. A classic example is the EU's REACH directive designed to offer people the optimum safety in a world that surrounds people with a diversity of chemicals that have not always been tested comprehensively or as the cocktail they create in the life of a modern person.

But research turned up by toxicologist Dr. Thomas Hartung, at the time working with the EU's Joint Research Centre, showing far more animals would need to be used in testing as a result of the more stringent rules in REACH, was suppressed. This, doubtless, was in the knowledge that such emotionally charged information would be used by those with a vested interest to kill REACH.

The German European Commissioner at the time, Gunter Verheugen, said at the time that REACH would not be ethically viable if it required excessive additional use of animals. The ethics of exposing humans to chemicals that were not as comprehensively tested did not appear to be an issue.

The legalising of soft drugs such as cannabis is another case in point — accepted as playing a malevolent role in some people's mental health, causing businesses to lose productivity, on the other hand being banned contributes to its scarcity and lack of control and so contributing to crime. The argument can be made for legalising it with

the added value of having the trade contribute to the state's coffers.

Alcohol is another case in point. It contributes to 3.3m deaths or 5.9% of deaths globally a year. There was a 240% increase in liver disease between 1995 and 2007 in Ireland, my own country, where ironically we have the highest abstinence rates in the EU.

This is all serious stuff, especially if you are a victim. Does it justify a *'nanny state'*? Will education about its safe use and dangers appease our feeling of needing to do something? Does the state and society confine itself to just tackling addiction? And where is the line between addiction and simply spending a boring retirement in a mindless stupor or alleviating pressure or simply being the life and soul of the party? Dr Baker and Dr. Bridgman touch on this.

Of course who pays for research should not influence either the scientist or the public perception, as Paul Skehan argues. **But experience shows that he who pays the piper expects to call the tune** and in an era when pharmaceutical companies do not want to publish their studies, or publish them selectively; when questions as well as answers are changed in Eurobarometers; or when scientists are plainly for hire, this may not be the place to start.

When the battle is on to continue not to have to list the ingredients of alcohol or of cigarettes clearly displayed so consumers know what they consume, one has to wonder what is to hide, and why?

Basically the system has broken down, the old world has disappeared giving rise to a deep and unbridgeable divide between the professionals and the citizens, with vested interests manipulating a political class fed on buzz-words, the latest fad, or their own greed for power or wealth.

The scientists are at one another's throats and many are at war with the decision makers — see the latest open letter published in Nature, *(http://openletter.euroscience.org/open-letter/)* described thus: *"Scientists from different European countries describe in this letter that, despite marked heterogeneity in the situation of scientific research in their respective countries, there are strong similarities in the destructive policies being followed. This critical analysis, highlighted in Nature and simultaneously published in a number of newspapers across Europe, is a wake-up call to policy makers to correct their course, and to researchers and citizens to defend the essential role of science in society."*

The increasing scepticism of citizens towards their main-steam politicians is evident at every election while the results of allowing the market alone to dictate is also evident in the obesity, diabetes and decreasing mortality rates. Prof. Kinderlerer explores some of the reasons why. And journalism as a provider of the tool to help citizens to understand how they are being governed — information — is in decay.

When vested interests spend millions of Euro to sway politicians and policies to their advantage, then there are alternative questions to be posed before we are entitled to insist that policies be science-based. The scientists and their employers must first ensure that their science is not policy-based.

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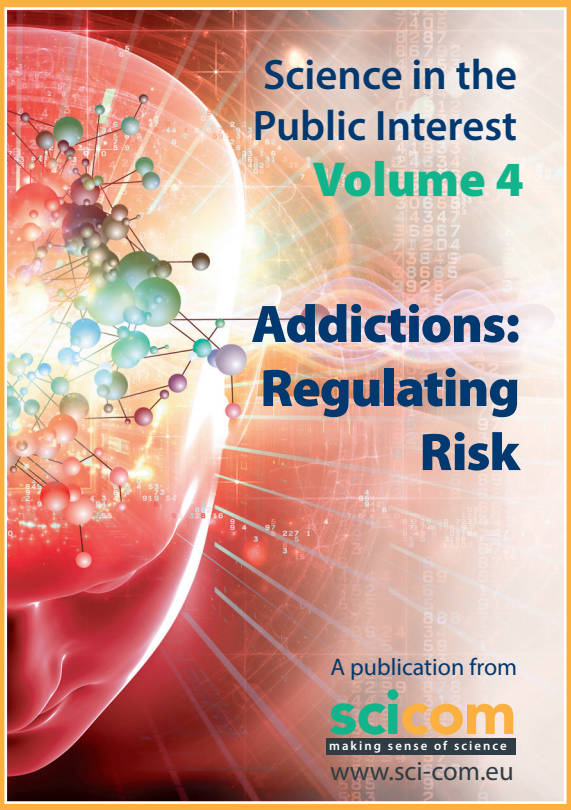

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