Science in the Public Interest
Volume 1

Harm Reduction

A publication from

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Editorial

**Evidence-Based Policy Versus Policy-Biased Evidence:
15 Key Recommendations**

Aidan Gilligan, Founder & CEO, SciCom – Making Sense of Science

Perspectives

Evidence-Based Policy Versus Policy-Biased Evidence:

The Challenge of Feeding Scientific Advice into Policy-Making

Harm Reduction Science

Key Findings and Recommendations

High-Level Consultation Event

Brussels, June 2012

"Harm reduction is the right thing to do".

Professor Anne Glover, Chief Scientific Adviser to European Commission President José Manuel Barroso.

Aidan Gilligan, Founder & CEO, SciCom – Making Sense of Science
Euroscience Governing Board Member.
Email: ag@sci-com.eu

WHY WE DO WHAT WE DO

Having worked for ten years as a specialist communications contractor and direct employee at the headquarters of the European Commission's in-house science service, the Joint Research Centre and its sister Directorate-General, Research & Innovation, I decided to try something new where I could make a real difference on the issues that concern me most. Harm reduction science is one of these. I'm no scientist or expert, but I know what the general public is interested in and want to pay their taxes for. Life and death is certainly one of them.

I had worked on EU-funded research events for years, focusing on topics ranging from mitigating natural disasters and launching hydrogen fuel testing facilities, to R&D Investment Scoreboards. You name it, we had seen it and done it – or at least claimed to have partially funded it. But had we ever made a discovery that really mattered? Were we interested in the big killers, those lifestyle-related killers that are preventable? Were we too busy testing food ladles from China or chasing pie-in-the-sky nuclear energy projects like ITER? Had we lost sight of what really mattered? I thought so, so I decided to be different.

SciCom – Making Sense of Science was born on 1st January, 2011 (www.sci-com.eu). It practises a brand of science diplomacy that adds essential value to the activities undertaken by science or trade ministries, the science services of international institutions or the flagship delivery teams of global conferences. Scientific integrity is core to its corporate identity. Within its network, it can reach out to and assemble unrivalled expertise around issues that very often divide the scientific community. It does not lobby or trade on its associations or try to influence the science it is simply helping to communicate.

That said, it does not try to blend in either. Once a year, SciCom organises a flagship Consultation Event around a topic that is perhaps the 'new black', which appears to offer great promise. At the same time, it might never take off 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 risk for the general public 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, do the right thing.

You can be the judge of that and come to your own view of the fifteen key recommendations that came out of our first 2012 endeavor on Harm Reduction Science, detailed below. They are supported by five seminal essays offering further perspectives from some of the participants and guest authors.

HOW WE DO WHAT WE DO

On 28th & 29th June, 2012, in Brussels, SciCom convened twenty-seven eminent European, African and American-based thought-leaders from fifteen countries. All were carefully selected and approached at the highest level to guarantee a maximum pool of relevant expertise, perhaps never before brought together in a single room. Participants included, amongst others, Chief Scientific Advisers; senior EU scientific officials and the chairs of their independent scientific advisory panels; representatives of national governments, academies and agencies; prominent business leaders;

stakeholders from pan-European scientific organisations and patient groups; senior editors from peer-reviewed health journals; and various distinguished figures from internationally renowned research facilities *(see page 12)*.

Of particular note is the fact that the drugs/pharma and alcohol industries were at the table but the nicotine/tobacco industry was barred from the meeting. It was a condition imposed by the EU's Directorate-General, Health & Consumers (SANCO) in return for its presence and that of two of its independent chairs. The passage of the Tobacco Framework Directive through the European Commission's internal consultation process forbade engagement at any level.

Critically, this gathering did include Professor Anne Glover, the newly appointed Chief Scientific Adviser to European Commission President José Manuel Barroso, and Professor Patrick Cunningham, the then Irish Chief Scientific Adviser and Champion of ESOF 2012 Dublin. In addition, Dr. Wilson M. Compton (American), Director, Division of Epidemiology, Services and Prevention Research, US National Institute on Drug Abuse (NIDA) gave an introductory, cross-cutting presentation on harm reduction insights in the United States. Dr. Delon Human (South African), President & CEO, Health Diplomats, Adviser to the UN Secretary General and former Secretary General of the World Medical Association gave a second introductory presentation on harm reduction approaches in the EU.

The Consultation Event's format was equally novel and designed to produce new thinking. Small working groups of five participants were pre-assigned under a Discussion Lead. Their task was to address a specific science-policy question before coming to Brussels. The Discussion Leads then presented common findings and individuals from their group were free to express further ideas or points of discord. These recommendations were then discussed by the entire group and further insights added before the Co-Chairs helped crystallise thinking and we moved on. Group consensus remarks were noted by two Rapporteurs and circulated post event. Comments and additions were then made within an agreed window of time before three key recommendations for each of the five pivotal questions were taken as the final outcomes.

THE FIVE PIVOTAL QUESTIONS WERE:
▸ What should we expect from the scientific community?
▸ What are the factors taken into account by the policy-making community?
▸ What needs to improve from the perspective of third-parties and interest groups?
▸ How should scientists, policy-makers and third-parties work together to manage risks and uncertainties at the same time as promoting innovation?
▸ What needs to happen next?

The aim was to encourage real engagement between individuals who might otherwise find themselves and their organisations on different sides of the fence. The common thread was identifying best practices and pitfalls based on real-life experiences. Importantly, SciCom's facilitating approach was never to look in-depth at the intractable issues around specific areas of harm reduction such as concrete approaches to mitigating use of drugs, alcohol or tobacco. Everything was done deliberately to avoid a top-down approach and pre-judging the outcomes. The emphasis was on equality, open discussion and the harvesting of ideas while reaching firm conclusions about the challenge of *"evidence-based policy versus policy-biased evidence".*

HARM REDUCTION SCIENCE AND POLICY: A MESSAGE FROM BRUSSELS

OUR 15 KEY FINDINGS WERE:

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 and policy is never straight-forward;

WHAT WE EXPECT FROM THE SCIENTIFIC COMMUNITY

4. The integrity of science needs to be positively asserted;

5. Stronger emphasis must be given to the inclusion of social sciences to improve understanding of how the public may react or adapt;

6. Scientists must learn to use established communication channels for providing policy advice more effectively and be less aloof and perhaps less arrogant;

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 and 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 and pitfalls encountered elsewhere;

WHAT WE EXPECT FROM THE PUBLIC, INDUSTRY AND 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 harm reduction;

14. Policy-making must learn to cope with the speed of scientific development and include greater foresight and policy anticipation;

15. Investment in harm reduction science is "the right thing to do".

BASED ON THESE FINDINGS, OUR 15 KEY RECOMMENDATIONS WERE:

SCIENCE AND POLICY – A CRUCIAL RELATIONSHIP

1. Science is a fundamental pillar of knowledge-based societies:

Science provides innovation, technological development, and ultimately benefits to humanity. Science is also a value per se, expanding the frontiers of knowledge and should not only be judged in economic terms.

2. Science can help provide the evidence base for sound public policy:

In an ever more complex and globalised economy and society, the importance of sound science is growing. Yet, it should be accepted as just one element in decision-making. Governmental decisions are ultimately political. Contrary to scientists, policy-makers are elected, which gives them the right *(and the duty)* to take decisions.

3. The dialogue between science and policy is never straight-forward:

Policy-makers have multiple sources of solicited and unsolicited advice, thus science can rarely speak with one voice. Stakeholders should see this as having both positives and negatives. Above all, there needs to be greater realisation that Eureka! moments are few and far between. Scientific evidence is not always welcomed by policy-makers, which can lead to it being ignored or distorted.

WHAT WE EXPECT FROM THE SCIENTIFIC COMMUNITY

4. The integrity of science needs to be positively asserted:

It must be independent and transparent. Vested interests must be disclosed and conflicts of interest avoided or managed appropriately. The integrity and quality of science should be nurtured, both individually and as a whole, by underpinning it with continuous peer review. It should not be optimistic or pessimistic but accurate and strive for greater inter- and multi-disciplinarity.

5. Stronger emphasis must be given to the inclusion of social sciences to improve understanding of how the public may react or adapt:

This will further help scientists understand their role in society. Their collective wisdom is essential in more proactively helping policy-makers to get things right. Science must accept that such inputs are often required ad-hoc, as there is not always time for tailor-made studies or optimal solutions.

6. Scientists must learn to use established communication channels for providing policy advice more effectively and be less aloof and perhaps less arrogant:

In so doing, science must enhance its voice, be courageous in policy debates, and get better organised to ensure more accurate representation of its findings. In particular, scientists need to understand that policy-makers have to constantly weigh up the pros and cons of every decision. By developing comparative analyses of choices based on scientific evidence, more pragmatic choices will be possible. Ultimately this will require a greater understanding of, and earlier engagement with, the general public, private sector and non-governmental organisations, who are equal stakeholders.

WHAT WE EXPECT FROM THE POLICY-MAKING COMMUNITY

7. Policy-makers must be receptive to scientific advice, even when this advice is uncomfortable:

They should involve scientists at all stages in the policy-making cycle and pose the right questions in a timely fashion, as the quality of advice can be determined by the necessary speed of response.

8. For the science and policy relationship to work, policy-makers have to challenge science to deliver on their public investment:

In so doing, policy-makers must not look at aspirations only, but should define explicit goals. Individual organisations or states might find this easier than larger supra-national groups that tend to shy away from target-setting.

9. Policy-makers should consult more widely and learn from best practices and pitfalls encountered elsewhere:

They may be restricted in the level of expertise or tools they have at their disposal. Nevertheless, they should keep their door open and more readily include the private/corporate sector and civil society groups/NGOs in public dialogue on scientific evidence.

WHAT WE EXPECT FROM THE PUBLIC, INDUSTRY AND INTEREST GROUPS

10. The public plays a critical role in determining what positions policy-makers will take:

Policy-makers are, by and large, elected and few will take a stance against the views of their electorate to support what the scientific evidence is telling us. This explains why industry and interest groups spend so much time and resources trying to influence public opinion. Scientists must learn to find transparent ways and means to counter-balance this if the messages being passed are scientifically incorrect. Even so, scientists have to realise that scientific consensus may not exist and avoid framing issues as science versus the public with science in the right. The public, also, must be more trusting of science and be made to understand that societal problems are not necessarily problems with purely scientific solutions. Crucially, they need to value innovative science and accept that calculated risks are fundamental to realising proven benefits.

11. Industry is the largest investor in science and has every right to have its voice heard:

Industry expects that the policy-making framework is set up to facilitate its success which is both economic and societal. Industry should strive for better practice in disclosing its vested interests and avoid conflicts of interest when engaging with external scientists and policy-makers. Above all, industrial research should be underpinned by an inherent integrity and quality. It should avoid a battle-ground mentality and the promotion of public disinformation to muddle the scientific picture when competitors or policy-makers appear to be going in a direction it may not prefer.

12. Interest groups similarly have every right to have their voice heard as guardians of the common good or legitimate sectoral interests:

Industry groups are a crucial cog in the policy-making cycle. They must be transparent and accountable but above all, responsible for the information and misinformation they disseminate to suit their purpose. 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 clearly wrong, they should learn to hold their hands up and contribute to dismantling the public myths about science they have helped create.

WHAT NEEDS TO HAPPEN

13. Scientific advice must be more involved in all stages of the policy-making cycle, particularly in harm reduction:

Particularly in Europe, from policy-anticipation and development to policy-implementation and evaluation, scientists need to be more readily seconded into political circles. This is the US model where every elected official in Washington has an independently vetted scientist allocated to their staff. This interaction will help bridge the gap whereby scientists tend to think long-term while policy-makers tend to think in short-term categories *(election cycles)*. At the same time, scientists think on all spatial scales - from the atom to the universe - while most policy-makers rather care for their constituency.

14. Policy-making must learn to cope with the speed of scientific development and include greater foresight and policy anticipation:

Aspects of future risk and uncertainty are particularly complex and difficult for policy-makers to grapple with. Science should be more forthright in providing advice on the costs and benefits of action or inaction. Similarly, the precautionary principle must not be misused for impeding technological progress around reducing harm.

15. Investment in harm reduction science is *"the right thing to do"*:

An increased focus on harm reduction science and innovation will help prevent disease and premature death and promote health in the EU and worldwide. For this to be further established, there is a need to build trust between scientists, policy-makers and other societal actors through a long-term, sustained and participatory dialogue. Nobody should be excluded or left behind. There is a need for institutions that can serve as "brokers" and "interpreters" between the science and policy arenas. Global challenges need global solutions. It is therefore of the utmost importance to join efforts globally to provide the best possible scientific solutions for our time.

WHAT THE EXPERTS SAID

The backdrop to the **Consultation Event** was an acceptance that societal problems such as the misuse of illicit drugs or alcohol are not necessarily problems with purely scientific solutions. Speakers argued that innovation in science such as new brain research is ever more prevalent and important in shedding new light on how the three strands of biological, psychological and social elements work together.

Harm reduction science is evolving. During specific case-studies on, for example, drug addiction in the USA, new research has shown that while genetics plays a part, this is only one part of a more complex picture in which environmental factors are also important contributors. Personalised medicine also provides a research opportunity to demonstrate the link between genetics and disease. However, establishing a relationship between genetic variation and behaviour is a greater challenge.

All participants agreed on the importance of continued global research into the brain-reward circuitry, particularly the unknown underlying mechanisms behind compulsive behavior and addiction-like neuro adaptive responses. We are only beginning to understand the role of reward and reinforcement mechanisms and how it is established in memory formation, particularly during our youth.

An underlying tension remains between individual - versus population-based sciences - when deciding policy. In some countries, elected officials can more easily make the case for harm reduction *(e.g. free needle exchange)* in illicit drugs when it is clearly explained that both the user and the general population may face a greater risk of HIV. But on the flip side, in other countries, asking voters to fund free needles or methadone treatments is akin to asking them to stick the needles in their own eyes. What we see globally is a reticence to take such calculated risks and the precautionary principle is often the fallback position i.e. do nothing. However, these positive and negative experiences should not diminish the proven role and value of harm reduction measures in global health care for individuals.

Even if what we eat is less and less perceived as a personal choice, it is understandable that hard-pressed tax payers do not want to pay for the treatment of chronic diseases linked to dietary excess *(e.g. type 2 diabetes)*. Likewise, few accept that alcohol addiction is an excuse for unsocial behaviour.

If reduced harm is clearly possible at the product development stage *(e.g. e-cigarettes, alcohol-light products)* scientists and health practitioners must mobilise to accelerate the incorporation of such evidence into policy-making. The public often cannot fathom how a product is available on the market, harm is discovered and only then the fundamental research is carried out. In turn, this should help to better correlate public and private science funding to tackling pressing problems earlier on.

Policy-making should take better advantage of the jurisdictional and genetic diversity, for example, of the US and Europe, to test ideas and best practices within particular States or regions

before being more universally employed. This is the model currently adopted in the US by the National Institute for Drug Abuse. A rush for an EU-style *'one size fits all'* approach to policy-making could be restrictive in some cases, despite the strengths of the established framework.

The informed public, including scientists, increasingly express themselves via special interest groups. On the one hand, policy-makers need to embrace an inclusive, *'whole-of-society'* approach with genuine outreach to relevant stakeholders. Scientific outcomes are generally better when the industries being regulated are engaged in an appropriate way. On the other hand, powerful advocacy might intentionally or unintentionally result in the wrong scientific priorities. Private interests, in some cases, can be stronger than governments which may or may not raise questions about the democratic process.

Actual and perceived conflicts of interest also need to be addressed. Scientists are increasingly involved in public-private research or their own commercial endeavours - simply because they have to for funding. A past relationship with a specific industry, no matter how tentative, can result in exile from advising governments and international organisations alike.

If managed appropriately, this perceived conflict can actually be used as a benefit. Knowledge of industrial research is more often a plus, not a negative. Private research also plays the key role in frontier science and often sustains fragile scientific networks. Independence rules thus need to be more flexible. A reduced pool of experts is already perceived as a threat to areas of EU policy-making. It is clearly detrimental to decision-making, especially with regard to complex, niche health issues. **This is clearly not in the best interest of policy-makers and ultimately consumers.**

Furthermore, inviting civil society and industrial representatives with the necessary skills onto scientific advisory panels should be less exceptional. In short, we need to redefine the voice of industrial partners and third parties with science, while all should hold elected officials to the promises they make. This is crucial. In tandem, policy-makers and scientists need to move away from a *'we know what is best for you'* culture. Examples of a more enlightened, multi-stakeholder approach are increasing. At the same time, civil society can risk becoming *'the experts'* and needs to be mindful of losing its activist role and mentality.

By its very nature, science raises more problems than it solves. All agree that it needs an overhaul away from a self-governing, self-regulating, *'publish or die'* approach with funding and prestige the key drivers. This is resulting in a herd-like rush into a given topic, data deluge rather than data cooperation and too little reflection. As a consequence, the deep-rooted academic reward system encourages gross fragmentation and the risk of silos within the sciences when a more integrated advice-to-policy model should be promoted. Scientists need to reach out and understand their specialised, but ultimately, civil society role. Scientific advice is for a purpose. The only way to achieve this is to radically redress how scientific priorities are formed by society as a whole and the funding mechanisms underpinning them.

Keen not to assume that scientific consensus can exist or to frame issues as science versus the public with science in the right, the overriding consensus was that more needs to be done, particularly by influential groups like the European Institutions and their research resources, to guard against the underutilisation or misuse of science in policy-making.

The European Commission's Horizon 2020 Framework Programme provides a step in the right direction with a new, more open stakeholder model. But Horizon 2020's 'Grand Challenges', such as hunger and poverty, are largely problems of the past in the developed world. The most pressing challenges today are linked to lifestyle. Yet, the EU appears to be behind the curve. These challenges are of our own making. We can undo the harm we do to ourselves. More thought needs to be given to the creation of specific Harm Reduction Units and the allocation of resources

within the EU's own in-house scientific capacities.

To achieve this, greater political and scientific leadership is required to nudge the general public in the right direction. Until now, resources, policy priority-setting and media attention have overly focused on the debates around perhaps less urgent issues such as climate change, nuclear energy, GMOs, stem cells, creationism etc. Are these life-threatening?

Harm reduction science aims to save hundreds of millions of lives. This is where the role of a Chief Scientific Adviser, pulling the EU research family and external stakeholders together to see what is essentially being done, or a new pan-European research fund or Agency looking explicitly at harm reduction science, make perfect sense.

THE SCIENCE COMMUNITY MUST SHARPEN ITS MESSAGE & ENGAGE THE PUBLIC

For me as convener, the Brussels discussions underscored how the role of scientific advice in policy-making worldwide is growing. Yet, governments and global institutions face challenges in terms of how science is viewed and used. The trust gap between public perceptions and scientific realities needs to be addressed using sound science and effective communication of the evidence.

Policy-makers want to know the facts and receive independent advice while remaining conscious of their own election cycle. Yet, faced with claims and counter claims from interest groups - including science - this is not always obvious. And even when the scientific evidence is 'indisputable', decision-making is often muddied by a constant information/misinformation battle-ground. Panelists framed this as a 'Cain and Abel' contest between those supporting *"evidence-based policies"* (establish the science first, then inform the policy) versus those supporting *"policy-biased evidence"* (establish the policy first, then find the science to support it).

Both sides would benefit from engaging more with the science coming out of industry, particularly in areas of harm reduction. In fact, there is a duty to get at the *'negative information'* both public and private funded research might be hiding. Above all, science must remain independent while *'bad science'* and spin must be challenged.

CONVENER'S CONCLUSION

In policy decisions, important factors beyond the reach of science are often involved: fear, hype, ignorance, profit, resentment, or economic and political advantage. We even learned that bad timing can be detrimental, evidenced by Directorate-General SANCO's *(Health & Consumers)* vetoing of any engagement with the tobacco industry.

What also can get lost in the mix is that science does not always have clear answers. However, 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 we take our duty to society seriously.

As Irish Chief Scientific Adviser, Professor Patrick Cunningham rightly put it: *"Policymakers should encourage scientists to speak out even when their research or assessment may be unpopular. Scientists should learn to stand up, shout up and when necessary, shut up. The voice of the rational middle ground should be louder."*

The last word of the Consultation Event was spoken by Chief Scientific Adviser to President Barroso, Professor Anne Glover and she encapsulated it all: *"Harm reduction is the right thing to do".*

My overriding impression of this initiative is that science and policy do have a crucial

relationship. But all too often EU officials and scientists think they are policy-makers. On the other side, policy-makers should not think they are scientists.

The greatest single mistake I see is that both groups fall into the trap of thinking that constant negative messaging on the harm caused by lifestyle choices is readily understood or sinks in. Look at the case of Europe's first smoking ban in Ireland. Nearly ten years on and the Irish Chief Medical Officer's 2012 Report shows a 3-4% total Irish population increase. The public know that these bad habits kill them but they still do it. Why?

To arrive at an answer, we need to know more about brain reward systems and compulsive behaviour. Personalised medicine provides plenty of research linking genetics and disease. But establishing a relationship between genetic variation and behaviour is trickier. How does over-consumption of high-fat food trigger addiction-like neuro adaptive responses in our brain-reward circuitry? Why are less than 25% of heroin users proven to be dependent, while other addictive substances need only one try for a permanent susceptibility to addiction to occur? How does nicotine work as the principal reinforcing component in tobacco smoke responsible for addiction?

SciCom's Second High-Level Consultation Event in this public health series tackles these issues head on. Titled: **Substance Addictions & Their Brain Reward Systems: Drugs, Alcohol & Nicotine** and held in Brussels in June, 2013, seventy-five experts in exactly this field were convened under the Co-Chairmanship of the United Nations Secretary General's Office and the US National Institute on Drugs Abuse, to examine many of the underlying mechanisms.

A full report of their findings is available at: www.sci-com.eu

LIST OF PARTICIPANTS (Titles as of June 2012): ▶ **1. Professor Michel Kazatchkine** (French), Professor of Immunology at Université René Descartes; Paris; Former Executive Director, The Global Fund to fight AIDS, Tuberculosis & Malaria (Panelist) ▶ **2. Dr. Peter Tindemans** (Dutch), Secretary General, Euroscience; High-Level Research Policy Consultant to the World Bank (Panelist) ▶ **3. Professor Klaus Bock** (Danish), Chairman of the Danish National Research Foundation (DNRF) and Champion, ESOF 2014 Copenhagen (Panelist) ▶ **4. Professor Riitta Mustonen** (Finnish), Vice President, Academy of Finland; (Panelist) ▶ **5. Professor Helmut Greim** (German), Chair of the European Commission's Scientific Committee on Health and Environmental Risks (SCHER) (Panelist) ▶ **6. Dr. David Budtz Pedersen** (Danish), Strategic Adviser, Ministry of Science, Innovation & Higher Education; Bid Coordinator ESOF 2014 Copenhagen (Observer) ▶ **7. Professor Dr. Karl Fagherstrom** (Swedish), Founder, Society for Research on Nicotine and Tobacco; Former Editor-in-Chief, Scandinavian Journal for Behavioural Therapy; Director, Smokers Information Center (Panelist) ▶ **8. Dr. Bogosi Mogale** (South African), South African Mission to the European Union (Senior Health Representative to the EU, South African Department of Science & Technology) (Panelist) ▶ **9. Professor Jim Bridges** (British), Professor of Toxicology and Environmental Health and Dean for International Strategy at the University of Surrey, Guildford, UK; Chair of the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), (Panelist) ▶ **10. Dr. Jan Marco Mueller** (German), Assistant to CSA Anne Glover (Rapporteur) ▶ **11. Mr. Alberto da Ponte** (Portuguese), President of The Brewers of Europe; Board of Directors of the European Foundation for Alcohol Research (Panelist) ▶ **12. Mr. Anders Olauson** (Swedish), President, European Patients Forum; Chairman and Chief Executive Officer of the Agrenska Centre (Panelist) ▶ **13. Mr. Pierre-Olivier Bergeron** (French), Secretary General, The Brewers Association of Europe (Observer) ▶ **14. Professor Anne Glover** (British), Chief Scientific Adviser to José Manuel Barroso, President of the European Commission (Convener) ▶ **15. Dr. Richard Horton** (British), Editor-in-Chief, The Lancet; Formerly First-President of the World Association of Medical Editors & Past-President of the US Council of Science Editors (Panelist) ▶ **16. Dr. Martin Seychell** (Maltese), Deputy Director General, European Commission, Health and Consumers (Panelist) ▶ **17. Mr. Daan Du Toit** (South African), Minister Counsellor (Science & Technology), South African Mission to the European Union (Senior S&T Representative to the EU, South African Department of Science & Technology), (Observer) ▶ **18. Mr. Aidan Gilligan** (Irish), Event Organiser & CEO, SciCom – Making Sense of Science (Rapporteur) ▶ **19. Dr. Wilson M. Compton** (American), Director, Division of Epidemiology, Services and Prevention Research, US National Institute on Drug Abuse (NIDA), (Panelist) ▶ **20. Mrs. Sophia Kuhn** (Swedish), Communications Manager at the European Food Information Council (EUFIC) (Observer) ▶ **21. Professor Martin Ingvar** (Swedish), Dean of Research, Professor of Integrated Medicine, Karolinska Institut (Panelist) ▶ **22. Dr. Delon Human** (South African), President & CEO, Health Diplomats; Secretary-General of the Africa Medical Association (AfMA); Formerly Secretary of the World Medical Association; Formerly Adviser to the WHO Director-General and UN Secretary-General (Panelist) ▶ **23. Dr. Susan Kentner** (American), Director of the Brussels Office of the Helmholtz Association of German Research Centres (Observer) ▶ **24. Mrs. Nathalie Moll** (British), Secretary General, EuropaBio (Panelist) ▶ **25. Professor Patrick Cunningham** (Irish), Chief Scientific Adviser to the Irish Government; Professor of Animal Genetics, Trinity College Dublin; Champion, ESOF 2012 (Chair) **MISSING FROM THE PHOTO:** ▶ **26. Dr. Theodoros Karapiperis** (Greek), Head of Unit, Scientific and Technical Options Assessment Panel (STOA), European Parliament (Panelist) ▶ **27. Mr. Frederik Wittock** (Belgian), Senior Director, Cross-Pharma R&D Communications, Johnson & Johnson Pharmaceutical Research & Development (Panelist)

FIRST, DO LESS HARM

Dr. Delon Human, President & CEO, Health Diplomats, Adviser to the UN Secretary General and former Secretary General of the World Medical Association; Author: *Wise Nicotine*

Email: delon@healthdiplomats.com

Dr. Human argues for a more evidence-based approach to harm reduction and a move away from the morals-based discussions of the past. Evidence for the benefits of harm reduction will need to be produced for harm reduction efforts to be sustainable, but these benefits cannot be ignored – as the binary *'quit or die'* approach demands.

Unfortunately, harm reduction has engendered some debate and controversy. The majority of the public health community still advocates abstinence as the only defendable goal, paramount to a 'control or ban' approach. The underlying philosophy is, for example, that we should all work for a drug-free or tobacco-free world. If we accept any kind of drug use to help reduce harm, it would be tantamount to accepting drugs into mainstream society. There are also concerns that these harm reduction techniques might lead to increased initiation of use, decrease in the cessation of harmful substance abuse, relapses for former addicts and the *"normalisation"* of drugs in society. For many, asking them to agree to free methadone clinics is akin to asking them to legislate for drug consumption. But it is vital that the global science community fully embraces harm reduction.

ON A HISTORIC NOTE: HARM REDUCTION IS JUST COMMON SENSE SCIENCE

It is incredible to think that due to the absence of harm reduction science and practice during the 19th century, women in childbirth were dying at alarming rates in Europe and the United States. Up to 25% of women who delivered their babies in hospitals died from childbed fever *(puerperal sepsis, later found to be caused by Streptococcus pyogenes bacteria)*. In 1843, Dr. Oliver Wendell Holmes in the UK postulated that these infectious diseases were transmitted to their pregnant patients through the hands of their doctors. In the late 1840s, Dr. Ignaz Semmelweis of Vienna came to the same conclusion. In the maternity wards of a Vienna hospital, he noticed that the mortality rate in a delivery room staffed by medical students was up to three times higher than in a second delivery room staffed by midwives. The reason was simple – the students did not wash their hands after leaving the autopsy room and were transmitting an infection from their cadavers to the women in labour. Both Drs. Holmes and Semmelweis, against great resistance, ordered their staff to start washing their hands with a chlorinated solution before touching patients, one of the first examples of harm reduction in Europe. In the Vienna wards, the mortality rate eventually dropped to less than one percent.

Today, the United States Centers of Disease Control and Prevention (CDC) call *"hand-washing the single most important means of preventing the spread of infection."* The World Health Organisation (WHO) now devotes substantial time and resources to prevention in this area with such initiatives as the annual *"Global Handwashing Day"*. It is believed that ingraining the habit of washing hands with soap before eating and after using the toilet would save more lives than any single vaccine or medical intervention, cutting deaths from diarrhoea by almost half and deaths from acute respiratory infections by one-quarter. Habitual hand washing with soap would make a significant contribution to meeting the Millennium Development Goal of reducing deaths among children under the age of five by two-thirds by 2015.

WHAT IS HARM REDUCTION TODAY?

It is useful to first understand the context of harm reduction within public health. Public health science aspires to **prevent disease, prolong life and promote health**. It does this through the organised efforts and informed choices of society, organisations in both public and private sectors, with more focus on prevention than cure. In public health, the interests of the population weigh heavier than that of the individual, which can cause tension between public health and the health professions, who tend to focus more on the interests of the individual.

The term 'harm reduction' refers to policies, programmes, projects and interventions, which aim to reduce the health, social and economic harms associated with the use of psychoactive substances, without necessarily expecting a reduction or cessation of use. It therefore recognises that there will probably always be people who engage in activities carrying risk. **In democratic societies there are often tradeoffs to be made and harm reduction is a significant public health alternative to outright prohibitions and bans.**

Below are several examples:

- The use of condoms and other preventive measures for dealing with HIV and other sexually transmitted diseases;
- Needle exchange programs to reduce disease and deaths for drug users;
- Tobacco harm reduction, where harm is reduced if consumers reduce consumption or switch from the most harmful tobacco products *(combustibles such as classic cigarettes)* to smokeless tobacco *(e-cigarettes, snus)* or even better, pure nicotine alternatives such as nicotine replacement therapy;
- Alcohol harm reduction *(responsible drinking)*;
- Hand washing in certain hospital and societal settings;
- Reducing environmental emissions and discharges *(not total elimination)* as steps to controlling and improving air and water quality, including providing industry with incentives for reducing such emissions;
- Requiring the use of seatbelts and other safety requirements in automobiles etc.

WHY IS HARM REDUCTION OFTEN A CONTROVERSIAL SUBJECT?

The problem is that there will always be people who engage in risky behaviour, no matter what the consequences to themselves or others might be. **We do not live in a perfect world where legislation or enforcement produces the desired results.** Those who support the principles of harm reduction seek to reduce or mitigate the health risks associated with these risky behaviours, rather than to eliminate them. They believe in advocating what I see as the four stages of harm reduction: don't start, stop, don't harm others, and don't harm yourself. It is this fourth and final stage that is hard for many to swallow, essentially why help the people who chose this lifestyle?

Those of us who belong to the rational middle ground in science understand that not all of the one billion smokers the WHO expects to die from their habit in the 21st century are to blame for taking up this habit. Evidence suggests that 7/10 are trying to quit. The same can be said of 'drug addicts' addicted to prescribed pain-killers. Based on known science, if policy-makers can oblige the producers of harmful products to remove some of this known harm at the source *(e.g. salt in processed foods, toxicants in tobacco plants etc.)* or to create the research conditions for them to innovate less risky products, surely this is where common sense should be leading us? Unfortunately, this is very often the case.

Harm reduction also highlights the conflict between societal and individual interests in health care. What constitutes harm reduction for an individual may not necessarily result in a net decrease

in harm for society as a whole. If a product is only marginally less harmful, but a larger proportion of the population uses it, the end result could be an increase in societal harm. A good historical example is fat-free foods. If the reductions in risk are large, however, there is likely to be a public health benefit even with a large increase in use. For example, the current UK and Irish debate on a unit-based price control on alcohol.

BROAD STRATEGIES USED IN HARM REDUCTION
Looking at those harm reduction areas where every citizen on the planet stands to gain the most, such as drugs, alcohol and tobacco, some broad strategies are employed:

▸ **Supply reduction:** Aims to reduce the availability of substances and interventions, to target production and distribution *(E.g. points of sale, liquor licensing hours, smoking bans, prosecuting the 'traffickers' of alcohol, tobacco or illicit drugs)*;

▸ **Demand reduction:** Aims to reduce demand for substances, leading to no use, less use, fewer users, or fewer high consumption users. Interventions target consumption *(E.g. anti-drinking/smoking/obesity public information campaigns)*;

▸ **Harm reduction:** Aims to reduce harms associated with an activity or substance use and interventions target risk *(E.g. distributing free condoms, wash your hands campaigns, reduced risk components e.g. improved filters)*.

In alcohol, further areas are targeted to reduce harm, e.g.:

▸ **Structural:** targeting macro level influences on behaviour such as laws, policies and allocation of resources designed to affect the total population or segments of it;

▸ **Community:** targeting the context in which substances are used and social norms;

▸ **Individual:** targeting the individual substance or potential user to change their behaviour. For example, in Canada some studies have shown that serving chronic street alcoholics controlled doses of alcohol reduced their overall alcohol consumption.

TOBACCO HARM REDUCTION
Although nicotine is the major addictive substance in tobacco products, it is also unfairly given the major blame for the disease and death caused by tobacco products. In terms of toxicity, it is the smoke that kills, not the nicotine. Tobacco harm reduction is taken to mean encouraging and enabling smokers to reduce their risk of tobacco-related illness and death by switching to less hazardous tobacco products. This switch could be short-term or long-term, partial or full, with the understanding that every time an alternative tobacco product is used in place of a cigarette, risk of tobacco-related illness and death is reduced.

HARM REDUCTION IN AIDS
The current course of the AIDS epidemic will only change if people infected, and those at risk of infection, make a concerted effort to adopt preventive measures. Harm reduction is well suited to play a positive role in AIDS prevention. Certain types of risky behaviours, such as unprotected sexual intercourse and sharing of hypodermic needles, exponentially increase the risk of contracting HIV and AIDS. Containment of the AIDS epidemic thus depends to a large degree on effecting change in behaviour and lifestyle to break the chain of transmission. Countries such as Uganda where HIV transmission was targeted using the so-called ABC message *("abstinence, be faithful and if you can't, use a condom")*, are a good illustration of the benefits of a harm reduction programme. Abstinence is undoubtedly the most effective preventer, but condoms to practice safer sex were recognised as useful in reducing transmission rates.

THE FUTURE OF HARM REDUCTION

Although the need for and benefits of harm reduction science, practices and policies seem compelling, health policy needs to change and support harm reduction and "safer products" for them to become successful. The challenge will be to strengthen research, harmonise evidence-based regulation between the EU member states and foster the development of consumer acceptable safer products.

It is encouraging to see a shift from a morals-based discussion about harm reduction to its scientific roots. This will ultimately provide a more robust framework for a discussion and evaluation of risky behaviours, risk differentiation and potentially reduced harm products, and how best to manage these risks in our modern society.

The sustainability of harm reduction as a policy will also depend on how evidence validates its benefits for the individual and society. What cannot be tolerated is an ongoing indifference to the potential benefits of harm reduction, especially in the field of drugs, alcohol and tobacco. **If there is clear scientific evidence that individual and societal benefit is gained from harm reduction, this should be fully embraced.**

PUBLIC HEALTH APPROACHES TO DRUG ABUSE TO MINIMISE DRUG-RELATED DAMAGE

Dr Wilson Compton, Director, Division of Epidemiology, Services & Prevention Research, US National Institute on Drug Abuse (NIDA)
Email: wcompton@nida-nih.gov

The development of an effective, evidence-based public health approach to drug abuse must be built on three key pillars, argues Dr. Compton. The first is an understanding of how drug use affects, and is affected by, developmental brain-behaviour interactions. The second is a clear understanding of patterns in drug abuse. Finally, it is important to understand how policies can be implemented differently in different areas – with differing effects.

Drug abuse is a subject that is often overshadowed by irrational bias, stigma and discrimination. A public health perspective on drug abuse, however, needs to rely on an evidence-based approach if it is to maximise population benefit and minimise population morbidity. Three key principles are essential to this process if a truly effective, evidence-based public health approach to drug abuse is to be realised:

▸ It must be understood that drug abuse and addiction are closely linked to developmental, brain-behaviour interactions;
▸ Public health efforts must begin by understanding changing trends in drug abuse;
▸ The policy environment interacts with and impacts individual behaviours and this pattern must be monitored to understand the real policy impact.

THE LINK WITH DEVELOPMENTAL BRAIN-BEHAVIOUR INTERACTIONS

Drug abuse and addiction involve multiple interactions between innate factors within the individual and various types of environments. These environments include intersecting and overlapping domains such as family, peer, neighbourhood, legal, and social levels. Each of these domains can influence an individual's propensity to use drugs and to progress from drug use to addiction in concert with intra-individual factors such as genetic predisposition, innate response to substances and innate temperament (REF). Adding to the complexity, these intra-individual interactions with the environment may occur at specific developmental stages. The stage of development when exposure to the different environments occurs can be very important in determining outcomes (REF). For instance, **a robust finding has been the observation that early exposure to a substance is highly correlated with later addiction** (REF). The implication is that developmental factors are essential to understanding addiction.

At its most basic, addiction can be seen as a developmental disorder which is (at least partly) determined by an individual's developmental trajectories. Interesting work has now documented that the pattern of an individual's development of self-control in childhood predicts health, wealth, and public safety *(Moffitt, 2011)*. Similarly, **addiction can be viewed as a disease of the brain.** This is illustrated in studies which document measurable differences in the brains of persons who are addicted to all substances compared to others (REF). It appears that the fine balance in connections that normally exists between brain areas active in reward, motivation, learning and memory, and inhibitory control becomes severely disrupted in addiction.

UNDERSTANDING CHANGING TRENDS IN DRUG ABUSE

A public health approach to drug abuse and addiction has to start by monitoring drug trends. Analysis of such epidemiological data provides clues about the causes of addiction and offers important guidance about where and how to focus treatment and prevention interventions.

For example, the Community Epidemiology Work Group (CEWG) at the U.S. National Institute on Drug Abuse identifies and interprets emerging drug trends in the United States. The experts in the CEWG interpret these trends through a local and regional lens based on the concept that drug abuse shifts at the local level. These local shifts are due to the interactions of social networks, including interpersonal and market forces which are now increasingly impacted by global forces facilitated via the Internet (REF). Without this level of local and regional understanding, an effective approach is much harder to achieve.

An area of major concern of late has included Prescription Drug Abuse, made particularly notable by an epidemic of unintentional drug overdose deaths in the USA in which recent increases in mortality have been correlated with increases in overall prescriptions for opioid analgesics (REF).

To address this epidemic, the public health perspective means that there is a need for new thinking about:

- ▶ Availability of drugs within homes and from friends and family;
- ▶ Unintentional misuse of medications as an intervention target in addition to their intentional abuse;
- ▶ The potential for direct overdose intervention by making naloxone more readily available;
- ▶ Relaxed attitudes and misperceptions about prescription drugs; &
- ▶ Drug disposal efforts to minimize environmental exposure to prescription-type agents (REF).

MONITORING THE SOCIAL & POLICY ENVIRONMENT FOR IMPORTANT VARIATIONS

A close monitoring of the social and policy environment is important in order to maximize population benefits. The tendency is to think of policies as uniform and with a single impact. **In practice, policies are implemented within different regions in different ways.** This variation allows assessment of the impact of policies by studying the different populations and may, of course, be based on the local situation which can demand variation in policies and their enforcement.

A model for tracking policies relevant to health in the substance abuse area is the Alcohol Policy Information System at the U.S. National Institute on Alcohol Abuse and Alcoholism (REF). The variation in alcohol-relevant policies *(like other substance-related policies)* across time at the state and local level allows thoughtful and useful evaluation of their impact (REF). An emerging area in the United States is the shifting approach to marijuana, with some 18 states having legalised marijuana for medicinal purposes *(and most recently in 2 states for personal recreational use)*. How these shifts will impact overall rates of marijuana use and the health and social consequences related to marijuana is important and is the subject of multiple research projects (REF).

The goal of public health policy is to minimise the damage caused by substances and to maximize the public health benefit. I believe that a more pragmatic and detailed approach, adhering to the three principles described above, will be crucial in the implementation of robust evidence-based approaches that will reduce morbidity and mortality.
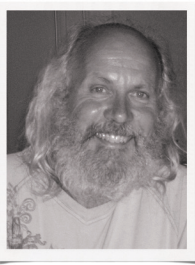
PUBLIC HEALTH APPROACHES TO ALCOHOL ABUSE TO MINIMISE ALCOHOL-RELATED DAMAGE

Andy Stonard, CEO, Esprit du Bois; Former CEO Rugby House – Drug & Alcohol Treatment Services; Author: *A Glass Half Full: Drinking - Reducing the Harm*
Email: andy@espritdubois.org

Alcohol is a major cause of harm on a global basis. But health policy and treatment responses have been inconsistent and ineffective, says Mr. Stonard. What is needed, he argues, is a complete overhaul in our thinking and a move away from the moral and economic approach which has dominated in the past. It is time, he says, to go much further in applying the increasing understanding that science is giving us.

Alcohol is a drug. Available - legally or illegally - in 90% of the world, it is produced and distributed via an industry network that includes farming, production, distribution, retail, entertainment and leisure, advertising and sponsorship. According to the World Health Organisation (WHO) and the International Centre for Alcohol Policy, between 30% and 50% of the world's alcohol output is privately produced and consumed. As a global phenomenon, alcohol requires interventions that are flexible and appropriate to widely differing regions and countries.

What does not vary, however, is the damage alcohol can cause, as the WHO reports: *"The harmful use of alcohol is a serious health burden, and it affects virtually all individuals on an international scale. Health problems from dangerous alcohol use arise in the form of acute and chronic conditions, and adverse social consequences are common when they are associated with alcohol consumption".*

Every year, the harmful use of alcohol kills 2.5 million people, including 320 000 young people between 15 and 29 years of age. It is the third leading risk factor for poor health globally, and harmful use of alcohol was responsible for almost 4% of all deaths in the world, according to the introduction of the WHO International strategy on alcohol harm reduction 2012 – 2020.

What is even more worrying is the fact that these figures do not include the much larger numbers of people who are drinking alcohol at levels that begin to put their lives at risk or who are engaged in alcohol-related behaviour that can put them at risk of accident, injury or infection.

How we drink and how we produce alcoholic beverages is different from Country to Country and how we try to tackle the harms associated with drinking alcohol is just as different, with the inconsistencies and differences highlighting a poor application of the science and knowledge that we do have.

The Economist online from the 14th February 2011 highlights this perfectly: **'The world drank the equivalent of 6.1 litres of pure alcohol per person in 2005,** *according to a report from the World Health Organisation published on February 11th. The biggest boozers are mostly found in Europe and in the former Soviet states. Moldovans are the most bibulous, getting through 18.2 litres each, nearly 2 litres more than the Czechs in second place. Over 10 litres of a Moldovan's annual intake is reckoned to be 'unrecorded' home-brewed liquor, making it particularly harmful to health. Such moonshine accounts for almost 30% of the world's drinking.'*

How to reduce these figures should represent key policy drivers. However, these figures are produced from a much larger Global pool of people who are drinking alcohol at levels that begin to put their lives at risk or are engaged in alcohol related behaviour and lifestyles that can put their lives at risk from related accident, injury or infection.

A good example of this can be found in the UK - *The 2012 Government Alcohol Strategy* details this breakdown in the following way.

We estimate that in a community of 100,000 people, each year:
  ▸ 2,000 people will be admitted to hospital with an alcohol-related condition;
  ▸ 1,000 people will be a victim of alcohol-related violent crime;
  ▸ Over 400 11-15 year olds will be drinking weekly;
  ▸ Over 13,000 people will binge-drink;
  ▸ Over 21,500 people will be regularly drinking above the lower-risk levels;
  ▸ Over 3,000 will be showing some signs of alcohol dependence; and
  ▸ Over 500 will be moderately or severely dependent on alcohol.

These figures are built on the Alcohol Harm Reduction Strategy for England and Wales from 2008 that states that there are over 8 million adults drinking over 28 units per week. The publication also acknowledges that 50% of stranger violence is alcohol related, 30% of child abuse involves alcohol, 50% of domestic violence and up to 80% of admissions at A&E at certain key times are alcohol related.

Analysis of data from Ireland's Hospital In-Patient Enquiry (HIPE) scheme has revealed a *"considerable increase"* in alcohol liver disease (ALD) morbidity and mortality between 1995 and 2007. Rates of alcoholic liver disease per 100,000 adults increased by 190% from 28.3 in 1995 to 82.2 in 2007, according to figures published in the journal, Alcohol and Alcoholism.

The figures also reveal *"considerable increases"* of alcohol liver disease among younger age groups. **Among 15-34 years olds, the rate of ALD discharges increased by 247%, while for the 35-49 age group, the rate increased by 224%** which did not surprise the researchers as 18-29-year-old drinkers have the highest level of alcohol consumption among Irish drinkers and two-fifths binge drink weekly.

However, the figures show that the majority of ALD discharges are still among the 35 to 64 age groups. Over two-fifths *(43%)* of all discharges were aged 50-64 years; 35% were 35-49 years old, 16% were aged over 65 years, while 6% were 15-34 years old.

The report found that while the majority of ALD discharges were male *(70%)*, there was a higher proportion of young females. This too was *"unsurprising"* according to researchers, as young Irish women *"drink in a manner similar to males with harmful drinking patterns, including weekly binge drinking common among this group"*.

The study found that increases in Alcoholic Liver Disease are consistent with the increase in alcohol consumption and harmful drinking patterns.

There is therefore a need to consider a twin track approach: one that is effective in reducing numbers at the chronic/severe end, and another which seeks to reduce the numbers at risk of harm *(30 to 40% of the population)* not only through alcohol-related ill health but also through accidents and injury, or violence by third parties under the influence of alcohol. Estimates vary, **but around 40 to 50% of violent incidents involve the consumption of alcohol** - with anecdotal evidence that the figure is higher still.

Addressing the reduction of harm in relation to alcohol needs to be at an individual, a national and an international level.

On an individual level, we are trying to bring about change in consumption patterns and in behaviour. In order to achieve this, individuals need access to good information so they can understand how to assess risk and how alcohol interacts on a chemical level at both a brain and motor neurone functional level. This requires the dissemination of simple science relevant to the

individual, while issues of lifestyle and associated health, economic and social considerations also need to be addressed.

To support this, governments need to provide the right information to help individuals understand the science. Government and public health also need to work in cooperation with industry rather than in opposition to it, through sensible regulation.

Most importantly, harm reduction strategies have to recognise the strong link between alcohol-related harm and low income. It is referenced in many studies around the World, but in all honesty, is mainly anecdotal. In the UK, Alcohol Concern, a national alcohol NGO stated in the 1990's that around **80% of overall alcohol harms are associated with the poorest 10% of the population.** What studies this was based on were never quoted but have gained acknowledgement and acceptance at many conferences. This figure cannot be supported by any one single piece of evidence but has never been challenged over 20 years.

What we require is nothing less than a complete overhaul of our thinking on the issue of alcohol and alcohol-associated harm. This paper describes the present approach – one which is based on economic and moral thinking rather than on the knowledge and understanding being generated by science and on a recognition of the clear role played by poverty.

PRICING AND SUPPLY

The use of taxation and duty to control alcohol consumption has been a principal tool for the last 5,000 years, along with supply control. Many governments refer to this as harm reduction at an economic level.

It is a reality that increasing price does reduce overall alcohol consumption. What it achieves is a reduction by the majority who already drink in moderation. For those already drinking heavily or who are addicted it makes matters worse. It raises their biggest cost *(drinking)*, with the result that other basic needs are neglected in order to maintain their level of drinking.

The economic and political argument is that this approach will affect future consumption levels. But what it completely fails to address are the behavioural aspects of drinking-related harm. Nor has it ever considered the effect of alcohol pricing on other drug markets. Our health based approaches are focused on the substance rather than on the people, who as consumers have an alarming tendency to change behaviour and habits when faced with market forces and policy and regulatory change.

What cannot be ignored is the fact that 'economic harm reduction' initiatives earn governments huge sources of revenue.

THE INTERNATIONAL RESPONSE

Under the auspices of the WHO, the key international strategy on alcohol harm reduction *(running from 2012 to 2020)* identifies ten key areas of policy options and interventions at the national level and four priority areas for global action.

The ten areas for national action are:
- Leadership, awareness and commitment;
- Health services' response;
- Community action;
- Drink-driving policies and countermeasures;
- Availability of alcohol;
- Marketing of alcoholic beverages;
- Pricing policies;

▶ Reducing the negative consequences of drinking and alcohol intoxication;
▶ Reducing the public health impact of illicit alcohol and informally produced alcohol; &
▶ Monitoring and surveillance.

The four priority areas for global action are:
▶ Public health advocacy and partnership;
▶ Technical support and capacity building;
▶ Production and dissemination of knowledge; &
▶ Resource mobilisation.

In the words of the WHO: *"The implementation of the global strategy will require active collaboration with Member States, with appropriate engagement of international development partners, civil society, the private sector, as well as public health and research institutions. WHO and its Member States are dedicated to work together to address the key areas of policy options and interventions, to interact with relevant stakeholder and to ensure that the strategy is implemented both nationally and globally. The progress of the strategy will be assessed at the Sixty-sixth World Health Assembly in 2013."*

Like many of these documents it is finely worded and based on clear common sense. The resources required for its successful implementation will be enormous, both financially and more importantly politically. But even at the most basic level it faces huge difficulties, as is demonstrated by the way in which different countries approach the issues of safe drinking levels and drink-driving regulations – two examples of the most fundamental application of the science we do know:

On safe drinking levels, a review appearing in Drug and Alcohol Today *(2013)* which looked at 57 countries *(including the 27 EU member states)*, showed that 27 countries had official low-risk drinking guidelines that could be expressed as grams of ethanol while many others did not have guidelines that could be expressed in this way. *(They encouraged moderate consumption and/or abstinence in certain circumstances - but did not define what this is.)* **Some countries did not have readily accessible alcohol guidelines at all - including eight EU member states.**

Moreover, there was variation in what was considered a *'standard drink'* or *'unit of alcohol',* ranging from 8g of ethanol in the UK to 14g in Slovakia. More guidelines expressed limits in terms of daily amounts than weekly amounts, and recommended maximum limits ranged from:

▶ 20g to 56g ethanol daily for men
▶ 10g to 42g ethanol daily for women
▶ 160g to 280g ethanol weekly for men
▶ 80g to 140g ethanol weekly for women

The ratio of recommended maximum limits for men and women also varied, with women's limits ranging from the same as men's to half men's limits. Where both a daily and a weekly limit were given for a country, the weekly limit was between three and seven times the daily limit. Some countries recommended having some alcohol-free days, or reducing daily consumption if drinking every day of the week.

Looking at the issue of drink driving rules, meanwhile, of 145 Countries reported on by the WHO, 14% *(21 countries)* allow no blood alcohol content (BAC). The countries which do allow some BAC vary as much as tenfold in what they allow.

In other words, despite the increasing understanding and knowledge provided by science and

research, we still have a far from adequate approach. We work within a framework of units of alcohol which focuses on amounts rather than understanding behaviour and the range of individual factors which can influence harm, from physical or psychological/emotional characteristics to cultural, genetic, age or income-related issues.

COMPLICATING FACTORS

To make matters worse, not only might a *'unit'* vary from country to country, it is also the case that within each country the established unit is then applied to every person from 18 to 80; from 60 kilos to 260 kilos, from someone in good health to someone else in poor health, on medication or not, on 100 euros a week or 1000 euros a week.

Then we have the issue of what constitutes harm in relation to drinking, or - more pointedly - what constitutes a problem that requires some form of recovery. What makes harm reduction a difficult concept across all substances is the fact that the overriding moral and political imperative is abstinence, based on the notion **'once an addict, always an addict'** and its accompanying idea that the addiction *(or illness or disease)* is only held in abeyance through abstinence. For many people this has of course been a successful path. Unfortunately, it also suits those politicians and others involved in health policy who cannot submit to the idea that, in drugs, substitute prescribing and needle exchange save lives and stop horrible infections. They are seen as being *'soft'* on drugs, and **the view is that someone wanting to cut down on their smoking or transfer to a less harmful practice is not as good as someone quitting.** Cutting down or reducing the harm just does not have the same ring to it.

Then comes the industry versus public health debate, where the industry is always portrayed as somehow the bad guy, no matter what they say, do or change. This has an interesting parallel with the *'addict'* who, even after 20 years clean, is still referred to as *'recovering'.*

For harm reduction to work, the public health sector and the wider industry *(farmers, producers, retailers and services)* have to work together. Like food and tobacco, alcohol is legal. The industry generates revenue for governments, its participants are regulated, are big employers and have close relationships with their customers. In Europe, our cities' regeneration and culture are hugely dependent on cafés, restaurants, bars and clubs.

The problematic dynamic for alcohol *(and tobacco)* is the contradiction between Treasury and Health and their inability to operate together under one government. **Good public health through harm reduction is surely compromised when there is an economic reliance on the sale and consumption of alcohol,** rather than a transparent and open dialogue on all aspects of the relationships.

WHERE IS THE SCIENCE IN ALL THIS?

We need a world that values evidence-based policy and treatment in place of the present reliance on policy-led evidence. The approach to alcohol treatment demonstrates this dynamic

The treatment industry for alcohol and drugs *(both private and public)* is based on *'successfully'* treating drink and drug users. These programmes can last for two, six, eight or even thirteen weeks. The differing durations appear to have little scientific basis and anyway appear highly questionable in the context that breaking up and overcoming an addiction typically takes around seven years.

In addition, Project MATCH* published findings in 1999 comparing treatment outcomes from three different treatment approaches: 12 step, cognitive behavioural and motivational enhancement. What it found was very little variance between the three - but huge variations in outcomes from the same treatment depending on where the treatment was carried out. Despite this evidence, these approaches still compete with one another fourteen years on.

*Project MATCH Research Group. *(1993).* Project MATCH: Rationale and methods for a multisite clinical trial matching patients to alcoholism treatment. Alcoholism: Clinical and Experimental Research, 17, 1130-1145.

The established treatment and health policy approach is constructed entirely around the individual, who is seen as having an individual illness or behavioural flaw. It ignores any wider factors and is based on a set of parameters that are politically and morally constructed rather than based on the science of what we know and what works. It is time now to go further in our application of science.

The importance of factors such as how we learn to drink, or what vulnerability we have – either genetically or through social learning – to any drug such as alcohol, is becoming increasingly obvious. This is not a black or white situation. There is no specific gene that creates an addictive personality. But there is emerging evidence that our genetic construction can make some of us more susceptible or vulnerable to anything *(such as alcohol)*, or lead to a greater impact on some aspect of our physical or emotional functioning, or contribute to organ weakness or chemical imbalance, all of which could create a string of interlinked and causal pathways.

We increasingly understand our neural pathways and understand what drug opens which receptor cells and the influences of various substances in our pleasure pathways, what triggers memories in our hippocampus and our brain reward systems. But these cannot be looked at in isolation because of the complex nature of cause and effect. For example, one the biggest impacts on drinking patterns and behaviour in Europe has, ironically, been the ban on smoking in public places. In achieving one goal, it has radically altered our drinking behaviour, with supermarkets encouraging the *'take home'* or *'carry out'* still further.

The science of psychology and how it is applied to us as consumers, as for instance in Nudge theory *(a concept in behavioural science and explained in Alberto Alemanno's accompanying paper)* gives us yet another angle on applying science to human behaviour.

Similarly, when we step outside the current 'western' therapeutic models of treatment and consider them more in the light of the science of anthropology and cognition and how our brains function through the senses rather than verbally, we begin to see new and potentially more effective interventions and understanding of self and behaviour through cognitive processes.

Lastly, the science of technology is harder to apply with alcohol than it is with drugs and tobacco. Clean needles, substitute prescribing and condoms in relation to drugs and infectious diseases have saved millions of lives, while of course electronic cigarettes in relation to smoking appear to have the same far reaching potential. However, for alcohol harm reduction to be effective then it cannot operate within a silo but as part of a wider harm reduction strategy, eloquently explained in Dr Delon Human's introduction.

SO WHAT WOULD WE NEED TO CONSIDER IN ANY BROAD AGREEMENT ON ALCOHOL HARM REDUCTION?

1. What information and research do we need to be clear who are the vulnerable groups at risk in society?
2. How do we want to encourage our population to drink in a way which enhances the enjoyment and leisure aspects whilst reducing the alcohol related violence and disorder?
3. How do we encourage our population to drink in less harmful ways to their health?
4. Once we know who these groups are then how are we to help them? What tools and information and practical support can they be given?

5. What does our public health information on alcohol need to contain and where should it be available?
6. Whose job is it to deliver these messages once we know what is needed and where?
7. What do our retail outlets need to look like in the wake of this new approach to alcohol and drinking?
8. What do we need to teach our young people and young adults?
9. What terminology do we need to have to effectively help people in the future and what do we need to abandon?
10. What treatment interventions do we need to have in place?
11. What medical services do we need to have in place to back up these treatment interventions?

RECOMMENDATIONS:

To develop a completely new alcohol health approach based on understanding how our brain works cognitively with alcohol. This allows us to understand behaviour and risk and can be individually assessed. This will also enable us to understand that some people are at greater risk because of their health, income, employment circumstances.

That public health and industry have to work together on policy, strategy, information, regulation and marketing. There can be no other way. This also has to include an acceptance that funding from the alcohol industry is no different to funding to pharma, trusts and even tobacco. All Government funding contains a rich seam of income from all of these legally based companies and interests. It can clearly be suggested that the problem we have is between the Treasury and Health. What we need is a concord between the public *(the consumer)*, industry, health and Government.

An open and informed public debate on alcohol, our use of alcohol and how we want to treat alcohol over the next century.

Improved funding for research and increasing what we know and what we need to know, with the EU supporting an independent body. The source of any money to provide research can and should always be non - consequential and there are good models already in existence for this. In the UK, there is an excellent model – NICE *(National Institute for Clinical Excellence)* – it is independent, brings in experts, reviews all the literature and creates best practice from this – there is one on tobacco harm reduction being released in June 2013 that the Tobacco Products Directive should adapt. In alcohol and drugs the guidance they have produced has been the best that there is *(in this author's opinion)*.

Actual implementation of what industry and government have already agreed in some countries – a good example is the agreement not to promote alcohol to under 18 years olds – sponsoring many sports events and teams must surely come under this yet is not applied.

Take alcohol out of its silo and consider it alongside drugs, tobacco and diet in relation to health, alongside criminal justice agencies for criminal justice and public safety, and as a key factor to be considered across all policies and strategies.

NUDGING HARM-REDUCTION
WHAT ROLE FOR BEHAVIOURAL RESEARCH IN PUBLIC HEALTH INTERVENTION?

Alberto Alemanno[1], Jean Monnet Professor of EU Law and Risk Regulation, HEC Paris

Email: alemanno@hec.fr

Drawing on the findings of behavioural science, *'nudge'* theory offers a positive way forward for harm reduction policy, argues Professor Alemanno. Replacing rigid rules and regulations with a more nuanced approach, *'nudge'* can help move the debate away from a morals-led, abstinence-only approach to a more scientific, pragmatic solution.

At a time when policy-makers want to change the behaviour of citizens to tackle a broad range of social problems, such as excessive drinking, obesity and crime, as well as climate change, a promising new policy approach has appeared that seems capable of escaping the liberal reservations typically associated with all forms of regulatory action.

Having relied on the assumption that governments can only change people's behaviour through rules and regulations, policy-makers now seem ready to design policies that better reflect how people really behave, not how they are assumed to behave as rational agents. The approach, which stems from the increasingly ubiquitous findings of behavioural science[2], is generally captured under the evocative concept of *'nudge'*[3]. Inspired by 'libertarian paternalism'[4], it suggests that the goal of public policies should be to steer citizens towards making positive decisions as individuals and for society while preserving individual choice. Acting as *'choice architects'* policy-makers organise the context, process and environment in which individuals make decisions. In so doing, they exploit some patterns of irrationality, often called *'cognitive biases',* to manipulate people's choices[5]. For example, inertia and procrastination are factors to be taken into account when designing *"default rules"* as people tend not to make affirmative choices. Behaviour patterns are also heavily influenced by the emergence of social norms as people are constrained by reputational forces and care about the perceptions of others. *"Framing"* and presentation of information are also strategic interventions to influence choices. Moreover, evidence suggests that salient and vivid warnings are more effective than statistical and abstract information[6]. Thus, rearranging the display of food makes it more likely that the healthy option is chosen. Indeed, **small, insignificant changes in the context in which decisions are made may produce beneficial effects for the public.**

It appears intuitive that this deferential approach, if applied to address individual risk choices, carries the potential to promote harm-reduction. This is because *'nudging',* in line with those who support the principles of harm-reduction, seeks to reduce or mitigate the health risks associated with these risky behaviours, rather than to eliminate them.

Under both US President Barack Obama[7] and UK Prime Minister David Cameron[8], administrative agencies have been encouraged to draw on behavioural and social sciences insights in the design or implementation of new regulations[9]. In a wide range of policy fields not limited to health but also including energy, financial services and transport, nudge presents a set of options that public institutions could use in connection with more traditional regulatory tools to produce behaviour change. As a result, behavioural sciences are set to inform the underpinnings of public policy and are doing so at a global level. There are several reasons for the global diffusion of this paradigm of governance: nudging looks like a cheap and smart alternative to expensive regulatory strategies[10];

its *"soft"* and information-based nature is easy to implement without major changes to the rigid regulatory structure; and finally it complements a radical reconsideration of bureaucracies in the informational State[11] brought about by Information and Communication Technologies[12].

The global appeal of behaviourally-informed regulation is due to several factors: private commercial organisations, in particular the new actors of the digital economy, are using behaviourally-informed strategies to affect the behaviour of consumers; **the use of behaviourally-informed regulatory strategies looks like a cheap and smart alternative to traditional expensive, yet often ineffective, regulatory measures**[13]; it promises to be choice-preserving, by always enabling the addressee to opt out of the preferred policy option; its *"soft"* and information-based nature is easy to implement without major changes to the rigid regulatory structure; and finally it complements a radical reconsideration of bureaucracies in the informational State[14] brought about by digital technologies which enable a more direct interaction between public administrations and citizens[15].

As a result, the emerging behavioural model of policy-making is based upon the premise that any sensible regulation system must consider how the findings of cognitive research might alter our understanding of the behaviour of citizens. In particular, its inclusion into the regulatory process should prevent policy-makers from making irrational decisions, either because of their own misperceptions or unforeseen reactions from the public.

Under this emerging approach, behavioural analysis is perceived as an opportunity to improve the efficacy as well as the efficiency of regulatory intervention, especially when – as it is often the case - it aims at behavioural change[16].

However, while behavioural research demonstrates the extent and limits of rational action, it does not provide regulators with a ready-made framework for incorporating its insights into policy-making[17]. It is also contended that the effectiveness of behaviourally-informed regulation is based on weak, almost anecdotal, evidence and its real impact may vary depending on the different cultural and social settings. Some scholars advocate the use of randomised trials to generate the evidence on which to ground the legitimacy of public interventions based on behavioural research[18].

In the light of the above, **it is worth asking what behavioural science has to offer to science-based policy-making, and in particular, to harm-reduction approaches.** More importantly how could it be integrated into policy-making? Would it be appropriate to develop administrative requirements prompting policy-makers to consider the findings of behavioural analysis while regulating?

This brief contribution tries to address these questions by providing some reflections on how behavioural research can be integrated into public health policy-making and, vice versa, on how public health policy-making can be adapted to the control of a *"nudging"* State.

By revealing as too narrow and ineffective regulatory techniques such as command-and-control to manage the state's increasing dependence on non-state actors, the emerging behaviourally-informed policy-making promotes a diverse view of state authority and its relationship with civil society and the business world[19].

Behaviorally-informed regulatory approaches are an attractive tool for public authorities for two basic reasons. They seem not only to lead to the design of more effective regulatory policies but also to preserve choice. While this is an important requirement for all policy interventions aimed at individual behaviours, it is particularly crucial in harm-reduction approaches as these do not mandate a particular behaviour but merely suggest a possible alternative. Second, their implementation being low-cost, they tend to be cheap. Yet, despite these promising qualities, these approaches are insidious.

Indeed, there is a the risk that without a rational mechanism to integrate behavioural research into policy-making the wealth of knowledge of this science will continue to have only a haphazard, anecdotal and small effect on the activities of public health authorities. At the same time, given the significant legal concerns raised by behaviourally-informed approaches, such as default rules and disclosure requirements, on citizens' rights vis-à-vis the Regulatory State, such a framework may also be needed to create a more transparent and accountable process for their incorporation into public health decision-making. Indeed, by their nature, behaviourally informed regulations present a dual quality: they both preserve and compromise freedom at the same time.

As witnessed by the US pioneering precedent, a general requirement imposed on public administrations could serve to accommodate in a more principled and consistent way the insights of behavioural science into policy-making while at the same time protecting them from possible abuses. In particular, it seems that the privileged framework for incorporating behavioural considerations into the regulatory process could be offered by regulatory impact assessment. Within this process of regulatory analysis, behavioural considerations may allow policy-makers not only to consider a broader set of regulatory options but also to empower citizens to have a say, thus increasing the accountability of the regulatory outcome.

Unfortunately the European Commission's proposal for a revised tobacco products directive only partly embraces behaviourally-informed approaches in its provisions. While most of the proposed tobacco control tools, such as combined graphic and health warnings, no longer aim to inform the public about the adverse effects of consumption but to change social norms, adjusting the *'choice environment'* to de-normalise tobacco, they do fall short with respect to the use of behavioural findings to promote harm-reduction approaches[20].

While the proposal focuses predominantly on tobacco, it also extends the directive's scope to include products that do not contain tobacco, but nicotine, such as electronic and herbal cigarettes. Their marketing material must now carry health warnings. In addition, e-cigarettes are subject to the same authorisation required for medicinal products. It also maintains the ban on oral tobacco products with the usual exception for snus in Sweden.

This stance on alternative products favours an abstinence-only policy and de facto rejects a risk-reduction policy of encouraging smokers to switch to nicotine-delivery products that carry less risk. This approach may appear understandable *(the fear of its proponents is that these products might become a gateway for future consumption)*. It also seems somehow inevitable, since Big Tobacco has earned mistrust. Nonetheless, it ignores millions of addicted smokers: they are left with only one choice – to continue to consume nicotine by smoking or not to consume nicotine at all.

Given the promises of behaviourally-based approaches to nudge smokers away from conventional tobacco products towards less-hazardous alternatives, the European Commission's abstinence-only approach is questionable.

While it is true that the science behind these *'safer products,'* such as snus and electronic cigarettes, still needs to be strengthened, it would be a shame should the ideologically-driven *'denormalisation'* imperative currently animating the public health community deprive society of the rationally-based, potential gains stemming from harm-reduction.

It against this backdrop that I believe that behavioural science may contribute to help shift from a morals-based discussion about harm-reduction to where it belongs: its scientific origin.

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STRIKING THE BALANCE BETWEEN SCIENTIFIC EVIDENCE AND POLICY-MAKING

David Budtz Pedersen[21], Co-Director, Humanomics Research Center, Aarhus University; Strategic Adviser, Danish Ministry of Science
Email: davidp@hum.ku.dk

Policy-making depends for its legitimacy on robust scientific advice, says Dr. Budtz Pedersen. But there has to be a fine balance between the roles of scientific adviser and policy-maker. It is not for scientists to make policy, or for politicians to bend or ignore science to serve their own political ends. Only if this balance is achieved can citizens be confident that they are getting *'evidence-based policy'* rather than *'policy-biased evidence',* as coined by Aidan Gilligan

Science-based policy-making has grown ever more important in recent years, in parallel with the dramatic increase in the complexity and uncertainty of the ways in which science and technology interact with society and economy at the national and global level. Installing a proper framework for ensuring the integrity of, and public trust in and support for, science is becoming an urgent task for European and global policy-makers.

People rightly expect politicians to be honest with the facts when they decide about public policies and future scenarios. This is why scientific evidence in policy-making is so important. In liberal democracies, policies are legitimate and accepted only if they are sufficiently justified, efficient and respectful of social and individual rights.[22] Various scholars and policy-makers have contributed to the discussion on what a workable compromise between science and democracy may look like. On the one hand, it has been argued that we should avoid what the political theorist David Estlund has called an epistocracy, that is, a society in which the experts rule over the democratic polity.[23] On the other hand, we should avoid dogmatism and any tendency towards irrational behaviour while making best use of the knowledge offered by scientific authorities and scientific guidelines. Science and democracy are based on a social contract shaped by different but often implicit social norms.

These norms can be schematised as follows:
1. In a well-ordered society, democratic decision-making and public debates must be informed by a scientific approach to the relevant facts.
2. Democratic decisions and public policies that deliberately ignore relevant scientific facts are illegitimate or otherwise normatively defective.
3. The scientific community must inform policy-makers about facts and findings, where this is relevant, but should leave policy-making to the democratic process. In short, there should be a certain division of cognitive and deliberative labour, roughly corresponding to the division between facts and values.

At various points, scientists are faced with normative questions, but it is not the task of scientists or experts to try to determine the right answers to these. Rather, in so far as policy decisions depend on normative questions, it is for the wider democratic community to determine how to deal with them.[24] Accordingly, simply listening to the best-qualified scientists for policy advice may not always ensure that research and development are conducted for the public good. Care must be taken to avoid the public paralysis that sometimes accompanies expertise. Studies of

disasters – **Challenger, Fukushima, or the financial meltdown – confirm that terrible events cannot always be avoided by listening to technical experts.** Instead a much wider institutional design of filtering and translating scientific expertise into policy-making is needed.[25]

"EPISTEMIC AND POLITICAL ROBUSTNESS" OF SCIENTIFIC ADVICE

Although it may seem obvious that policy should be informed by scientific understanding, and should therefore be evidence-based, this assumption is itself based on surprisingly little consensus or evidence. Debates continue, for example, about what exactly constitutes good evidence, where and how such evidence should be sought, and at what stage in the policy process different forms of evidence might be appropriate.[26] That such debate persists reflects the fact that there are many open questions about the nature of science-policy interactions. Therefore, we need to ask not just how science can best inform policy, but also how policy and political processes can support the institutional arrangements for producing robust and reliable advice.

Sheila Jasanoff's seminal study of science advisers shows that the value of science in policy stems in part from its capacity for detailed engagement with practical policy problems. At the same time, the authority of science depends on maintaining its independence from politics, in what has been coined as "boundary work".[27] In practice, however, experiences in different institutional contexts, both national and international, have brought about a much greater awareness of the processes of interconnection between science, politics, policy-making and the public.[28] Justus Lentsch and Peter Weingart have provided an important contribution to the debate on the institutional design of scientific advisory organisations. In the collected volume *The Politics of Scientific Advice (2011)* they argue that the particular connection between scientific experts and policy-makers should be identified as an institutional mechanism by which two different forms of justification are united: on the one hand epistemic robustness that pertains to the quality of knowledge and, on the other hand, political robustness that refers to aspects of responsiveness and political legitimacy. According to Lentsch and Weingart, scientific advice must be epistemically and politically robust at the same time. Expert knowledge communicated by science advisers has to have a dual reference. It is not enough simply to meet the standards identified by epistemic criteria of validity and reliability. Rather, scientific advice must be scientifically sound and politically relevant and legitimate at the same time.[29]

In this context, epistemic robustness refers to the quality of knowledge in the sense of its validity and coherence. As the knowledge generated in advisory bodies responds to political problems and, thus, usually transcends normal disciplinary knowledge production, it has to meet the requirements of exactness and validity and at the same time leave enough space for public deliberation and decision-making. Instead of packaging knowledge claims in a well-ordered body of expertise that leaves no room for discussion, **science advisers must open up science and consider the values, concerns, uncertainties and perspectives of those affected by the decisions and actions.** Still, knowledge that is uncertain and ambivalent may be epistemically robust if the probabilities of the claimed functional or causal relations are sufficiently reliable. Political robustness of knowledge, on the other hand, refers to the acceptability and the feasibility to implement recommendations based on it. An advice is robust if it can be politically implemented and meets the needs of the policy-makers. Political robustness thus implies that the knowledge and preferences of the affected stakeholders are taken into account.[30]

Distinguishing between the two dimensions of justification throws new light on two common assumptions underlying most advisory arrangements: first, it reaffirms that good or sound scientific knowledge provides the best possible foundation for public policy *(i.e. peer review)*, and second, it opens the way for scientists, policy-makers and citizens to engage in a common dialogue

regarding the political robustness and relevance of the evidence in question.[31] As Lentsch and Weingart further note, the quality of scientific advice to politics depends on the degree to which these two requirements of robustness are met. It is obvious that they cannot be met equally at the same time: *"The overall question is: which form must expert advice have, and in which institutional arrangements must it be generated and communicated to meet the dual requirements of political acceptability and scientific validity? Phrasing the problem in this way means that the quality of expert advice to governments is primarily an issue of organisational design. The focus is on organisational conditions because they influence the quality of advice and, at the same time, they can be shaped by scientists and policy-makers."[32]*

INSTITUTIONAL DESIGN AND SCIENCE ADVISERS

The question of the appropriate institutional design of scientific advisory bodies and how this affects the quality of the advice they offer, i.e. their capacity to bridge between science and politics, has been widely discussed in the scholarly literature as well as in practical policy-making. Upon taking office, the Obama Administration in the United States was strongly committed to promoting scientific integrity. On the basis of his concern that the sciences of climate change, stem cells, and evolutionary biology, were subject to political suppression under the former administration, Obama declared his intention to *"restore science to its rightful place."* Soon after he took office, he issued a memorandum outlining his administration's basic policy for scientific integrity and evidence. And US Science Adviser, John P. Holdren, later finalised a more detailed set of guidelines in collaboration with several government agencies for ensuring a wider use of evidence in policy-making. Worldwide, we have seen novel structures for scientific advice being established, both through new institutions like the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES) in the United Kingdom and through the appointment of Chief Scientific Adviser Anne Glover to the President of the European Commission. Add to this the various advisory bodies, covering a spectrum from think tanks, governmental policy-oriented research institutes to agencies and academies.[33]

The overarching need, particularly in the context of today's complex societal challenges, is not so much for specific technical recommendations, or for certainty in the face of environmental and social complexities, but for the capacity to reflect on and cope with uncertainties, while making clear what science can and cannot do. In other words, scientific advice is not merely a body of information but a dynamic process. This process should have a clear task and mandate, yet in practice the responsibilities of advisory bodies are many and diverse. Some institutions, such as the US National Research Council, act as scientific academies, providing independent advice. The German Science Council seeks consensus among stakeholders and citizens, while the Danish consensus model stimulates negotiations over policy options and emphasises compromise so as to enable dialogue and build public influence. These international trends also highlight the importance of different national cultures in shaping responses to demands for credibility and legitimacy.[34]

REBUILDING PUBLIC TRUST IN SCIENCE

In spite of its importance however, the access to fair and qualified scientific advice is sometimes troubled, and periodically erupts into public controversy. Prominent examples include the debate over scientific understandings of climate change, disputes over the use of genetically modified crops, the failure to acknowledge the risk of the Japanese tsunami and subsequent nuclear disaster, and the conflict over stem cell research, which is particularly acute in the United States.[35] Still more recently, it has been debated whether there is a risk that 'evidence-based policy' turns into 'policy-

biased evidence' with public research institutions and universities receiving an increasing part of their budgets in co-funding from the industry. Anne Glover, the Chief Scientific Adviser to the President of the European Commission, has said that she is *"extremely uncomfortable"* witnessing the lack of trust in some quarters at the role of industry in science. The suspicion that industry involvement in science is only geared towards profit threatens to derail European science. This is echoed in a recent Eurobarometer survey that documents that European citizens have lost confidence in science due to researchers' dependence on industry funding. Today, close to three in five Europeans (58%) agree that *"we can no longer trust scientists to tell the truth about controversial scientific and technological issues because they depend more and more on money from industry"* while only 16% of respondents at the EU27 level disagree.[36]

It is the role of the next generation of science advisers to find transparent ways and means to counter-balance this situation. Industry is the largest investor in science and should expect that the policy-making framework is set up to facilitate its success *(e.g. "Innovation Union," "European Technology Platforms")*. Yet, as Aidan Gilligan's Editorial argues, it is of great importance that science is independent and transparent. Vested interests must be disclosed and conflicts of interest avoided. Science must have an inherent integrity and quality, both individually and as a whole, underpinned by continuous peer review.[37] Above all, research should avoid a battle-ground mentality and the promotion of incentives to keep negative research results undisclosed, or to translate publicly funded knowledge into private intellectual property that is concealed from the public. In post-Fukushima Japan, policy-makers have worked out a number of guidelines for a robust system of linking scientific advice to public policies that may serve as inspiration for other countries. The Japanese Science and Technology Agency's Center for Research and Development Strategy has issued a policy proposal calling for measures to enhance the effectiveness and integrity of science-based policy-making. The proposal features a number of general principles on science-to-policy relations that is worth contemplating:[38]
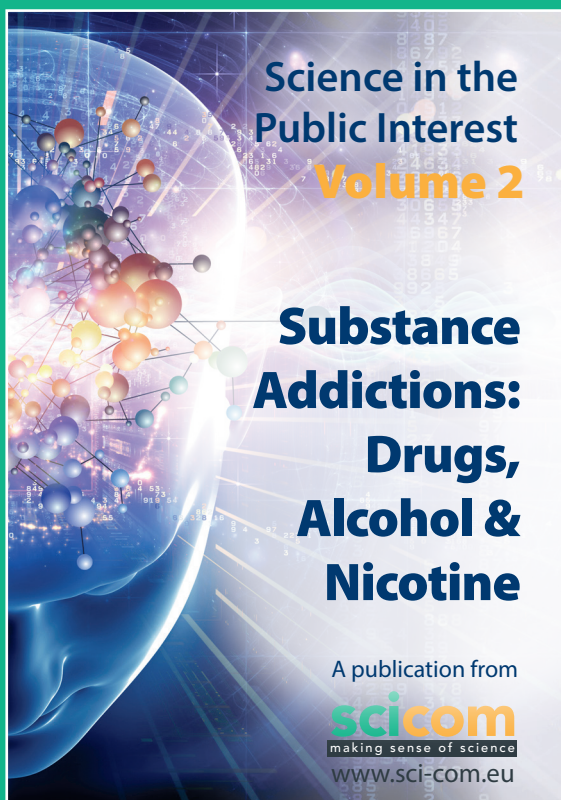
- ▸ **Seeking scientific advice in a timely manner.** The government must endeavour to identify policy issues that require scientific knowledge in a timely and pertinent manner and act to acquire the best scientific knowledge available.
- ▸ **Ensuring the independence of scientific advisers.** Policy-makers must not intervene inappropriately in the activities of scientists and experts. As a means to ensure objectivity and fairness, scientific advisers shall declare any potential conflicts of interest.
- ▸ **Achieving broad perspectives and balance.** When policy-makers seek scientific advice, they should strive to secure the participation of scientists with appropriate insight and experience matched to the nature of the issues and to obtain balanced and interdisciplinary advice.
- ▸ **Ensuring the quality of advice.** Scientific advisers must strive for a balanced treatment of observational and experimental results and of cited papers and should improve the quality of scientific advice through peer review.
- ▸ **Proper handling of uncertainty.** Scientific advisers must provide policy-makers with clear explications of uncertainties and diversity of views associated with scientific knowledge.
- ▸ **Even-handed treatment of scientific advice.** Policy-makers must treat the scientific knowledge they acquire with fairness. They should not commission scientific advice with any preconception, distort scientific knowledge, or intentionally add wrong interpretations when using advice in policy-making.
- ▸ **Ensuring transparency of scientific advice.** To improve the quality and reliability of policy-making, policy-makers must ensure transparency of the scientific advice process.

Scientific knowledge is an essential element in the policy process, and policy-makers must duly respect it. At the same time, scientific advisers must recognise that scientific knowledge is not the sole basis of government decision-making. In promoting relevant efforts and following normative principles such as those stated above, particularities of diverse policy and scientific fields must be given due consideration. Depending on national differences and scientific traditions, it is important to build greater trust among scientists, policy-makers and citizens through a long-term, sustained and participatory dialogue. Science advisers and other relevant advisory institutions can serve as *"brokers"* and *"intermediaries"* between science and policy arenas. With the increased focus among science policy-makers and funding agencies on the *"Grand Challenges"* of contemporary society, such as climate change, energy and food security, and sustainable resources, it is important to join efforts globally to provide the best possible scientific advice. Evidence-based policies are crucial for more effective and efficient policies and for addressing competitiveness and societal transformations. The effective implementation of *"Horizon 2020"* and related challenge-driven funding programmes requires strengthening the evidence-base and developing methodologies and tools that are oriented at assessing and translating scientific knowledge into the democratic decision-making process.

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