Luxembourg, October 2016

Bias and Conflict of Interest – Taking a Holistic Perspective

In various conversations with stakeholders involved with the provision of scientific advice to EU policy-makers and regulators, it became evident that there are grave concerns as to whether the process will continue to deliver on what is expected of it. Policy-makers worried that advice would be attacked by those who did not agree with it as being biased because of the provenance of the science or the associations of experts with industry, top experts feared that participating in panels would lead to *ad hominem* attacks, journalists worried about the extent to which they can trust policy-makers' claims that there is scientific basis for their decisions and industry felt that science is being politicised.

Given these broad-based concerns, The Huggard Consulting Group decided to organise a workshop involving an expert group in order to take a holistic view of the issue and incorporate the latest thinking on how conflicts of interest, whether they are financial, professional, ideological or come from other personal reward factors, actually influence decision-making and the associated provision of advice. This effort was supported by a number of interested parties, namely, Bayer CropScience, IFRA (The International Fragrance Association), FoodDrinkEurope and Plastics Europe. The concept and overall approach was also discussed with the European Commission and NGOs.

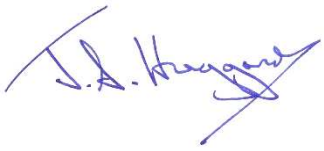
We first drafted a thought piece which was circulated to all participants for their consideration and which formed the basis for the discussion. Based on the workshop a report was drafted together with a short executive summary.

The following documentation contains the executive summary, the report from the workshop, the thought piece and the workshop agenda.

It is our belief that the findings of the workshop show that this issue of conflict of interest and the resultant bias is part of the human condition and that any attempts to address it by simply excluding certain experts from the advisory process will be counterproductive. This will likely lead to poor quality regulatory policy and damage to the credibility of the very institutions that the expert advice system was designed to support. The overall learning is that bias needs to be recognised, assessed and managed.

This workshop is just a starting point. The findings and recommendations need to be reviewed and communicated to a broad audience for their comments and feedback and then reduced to practice in the form of guidelines and procedures which can be made available by all who are engaged in managing the expert panels on whom our policy-makers depend for the best possible advice.

We are committed to continuing what we believe is this important work.



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THE HUGGARD CONSULTING GROUP

Ensuring that Policy-Makers and Regulators Access the Best Quality Scientific Advice

Managing Bias and Conflict of Interest

Expert Panel Discussion: Luxembourg, 10 October 2016

Background

Good regulation in the European Union depends on policy-makers and regulators obtaining top quality scientific advice. Officials seek to ensure that the quality of scientific advice is not undermined by conflicts of interest and their related biases. Current practice focuses primarily on economic conflicts.

Organised by The Huggard Consulting Group, an expert panel met to examine the issue of conflict of interests, and their related biases, in a holistic manner. The event brought together, under The Chatham House Rule, legal, behavioural, policy, ideological, scientific, and journalistic perspectives:

- **Aindrias Ó Caoimh**: Former judge of the European Court of Justice, who chaired the workshop
- **Dr. Shaul Shalvi**: Psychology Department, University of Amsterdam, Fellow, the Tinbergen Institute
- **Gareth Harding**: Adjunct Professor of Journalism and Managing Director of Clear Europe
- **Prof. Lucas Bergkamp**: Professor of Environmental Law and Partner at Hunton and Williams
- **Simon Bryceson MBE**: Senior political advisor and NGO strategist
- **Prof. Helmut Greim**: Former Scientific Committee Chairman/Member

The panel members considered the nature of bias and its complex causes. They examined the context in which scientific advice is provided to the European Union's institutions and discussed the extent to which current demands for both excellence and independence from financial conflicts of interest are in tension and increasingly prevent policy-makers and regulators from getting the best advice. Finally, panellists identified recommendations, based on the latest understanding of the nature of bias and how best to manage it, which could contribute to the development of excellent and impartial processes for the provision of scientific advice.

Overall Conclusions and Recommendations

- Conclusions:
    - There are many different forms of conflict of interest;
    - The bias that results from conflict of interest is part of the human condition and cannot be totally eliminated;
    - When selecting scientific experts, regulators need to address bias in a holistic manner, informed by behavioural science, with processes and procedures that recognise the potential for the resultant bias from all types of conflict of interest and seek to minimise it;

- Recommendations:
    - Set guidelines requiring the provision of scientific advice processes to be impartial and excellent;
    - Establish a process that combines transparency with an assessment of excellence (and relevance) when deciding who should participate in scientific advisory committees;
    - Ensure that all participants are aware of the potential for bias and establish disclosure mechanisms that enable a wide range of conflicts of interest to be identified;
    - Establish clear rules of procedure for assessing and managing bias from all sources;
    - Require all significant scientific assessments to be peer reviewed;
    - Set rules for data quality (including defining the characteristics of best available science and Systematic Review) that enable a true assessment to be made of the value and weight that can be assigned to a study.

The Huggard Consulting Group
October 2016

Ensuring that Policy-Makers and Regulators Access the Best Quality Scientific Advice

Managing Bias and Conflict of Interest

Part II:

Meeting Report

THE HUGGARD CONSULTING GROUP

Ensuring that Policy-Makers and Regulators Access the Best Quality Scientific Advice

Managing Bias and Conflict of Interest

Expert Panel Discussion: Luxembourg, 10 October 2016

Background

Good regulation in the European Union depends on policy-makers and regulators obtaining the best quality scientific advice. To achieve this and to ensure impartiality, officials seek to ensure that the quality of scientific advice is not undermined by conflicts of interest and their related biases. Current practice, reflected in the 2016 Commission Decision on Expert Groups, focuses primarily on economic conflicts. Scientific advances suggest that this approach may no longer be appropriate.

Organised by The Huggard Consulting Group, an eminent panel met in Luxembourg on Monday 10 October to examine conflict of interest and the resultant bias in a holistic manner. The event brought together, under The Chatham House Rule, behavioural, policy, ideological, scientific, and journalistic perspectives.

Using a thought piece developed in advance of the workshop, the panel members considered the nature of bias and its complex causes. They examined the context in which scientific advice is provided to the European Union's institutions and discussed the extent to which current demands for both excellence and independence from financial conflicts of interest are in conflict and, increasingly, prevent policy-makers from getting the best advice. Finally, panellists identified recommendations, based on the latest understanding of the nature of bias and how to best to manage it, which could contribute to the development of excellent and impartial processes for the provision of scientific advice.

Overall Conclusions and Recommendations

- There are many different forms of conflict of interest;
- The bias that results from conflict of interest is part of the human condition and cannot be eliminated;
- Current efforts to eliminate bias appear themselves, to be biased;
- When selecting scientific experts, regulators need to address bias in a holistic manner, informed by behavioural science, with processes and procedures that recognise the potential for the attendant bias from all types of conflict of interest and seek to minimise it;
- Recommendations:
    - Set out a standard for the provision of scientific advice that requires **processes** to be impartial and excellent;
    - Combine transparency with an assessment of excellence (and relevance) when deciding who should participate in scientific advisory committees;
    - Ensure that all experts are aware of the potential for bias and establish disclosure mechanisms that enable a wide range of conflicts-of-interest to be identified;
    - Establish clear rules of procedure for assessing and managing conflicts of interest within scientific committees;
    - Require all significant scientific assessments to be peer reviewed before final approval;
    - Set rules for data quality (including defining the characteristics of best available science and Systematic Review) that enable a true assessment to be made of the value and weight to be assigned to a study.

Bias and Conflict of Interest: The Science

- When scientific experts provide advice to policy-makers and regulators, bias occurs whenever secondary or private interests unduly influence judgements. This reflects a conflict of interest that inhibits the capacity of the expert to advise impartially and in the public interest;
- Arguing that bias may undermine the quality of advice and create a perceived lack of impartiality, governments have sought to avoid it by identifying, through a process of disclosure, evident financial conflicts of interest and, thus, excluding experts. Whilst this is the general approach, and the one used by the European Commission, good practice also requires the identification of other types of bias;

- Recent findings of behavioural psychology, suggests that this approach, with its primary emphasis on material reward factors, is out-of-date and incomplete;
- Instead, today's research suggests that personal biases, even for those acting in the public interest, reflect a wide range of personal reward factors/conflicts of interest. Such conflicts are complex and extensive. Some are conscious whilst others are not. They include financial, academic-professional ambitions, power, status, beliefs and ideologies, personal commitments and experiences, political affiliations, national cultures, and knowledge (or the lack of it);
- It is now considered more accurate to consider bias as part of the human condition because it provides a mechanism whereby information can be processed in a complex world. We all have it. Thus the problem facing officials is not how to avoid it, rather how to manage it.

Provision of Scientific Advice: The Context

- Findings of scientific committees are increasingly attacked. Often, this is not a debate about the scientific evidence specifically. It reflects underlying differences of values, a deep-seated lack of trust in government, because of historic regulatory failures, and scepticism about the motives of scientists linked to profit-motivated businesses;
- Within a rapidly changing media context that is eroding journalistic expertise and encourages sensation and partiality, perceptions of conflict of interest due to industry associations are rapidly amplified via simplistic reporting;
- EU institutions, when selecting scientific experts, tend to focus almost exclusively on financial conflicts of interest and by whom the science is produced. This is an understandable response to public concern and represents an attempt to build trust. However, by raising the prominence of financial links, instead of the quality of science, it encourages *ad hominem* attacks on experts and undermines trust in the utility of advisory processes;
- Regulators need the best available scientific advice because it provides the only credible means of identifying hazards, distinguishing real risks from perceived hazards, designing effective solutions, identifying benefits, and providing an evidence-based rationale for the use of regulatory powers. Without this knowledge, there is a risk of regulatory failure and consequent reduction in protection for citizens and the environment with a concomitant adverse impact on the legitimacy of the EU's institutions;
- Problems are already evident, as eminent scientists are increasingly reluctant to be involved in advisory committees. In their place, the "field" of available scientists now includes, for some controversial issues, less experienced scientists or those not working at the cutting-edge of research. With overemphasis on financial conflict, the pool from which acceptable experts are drawn is now more likely to see top experts replaced by scientists who act as advocates for social or political issues and members of activist scientific communities. Many of these scientists also face significant conflicts of interest and their involvement in provision advice may undermine perceptions of impartiality. Requirements for disclosure of irrelevant, historic financial information further undermines the attractiveness of public service for some eminent scientists;
- Relationships between academia and business have changed. Today, at least 85% of R&D carried out in the EU is either funded by business or involves partnerships between research centres (including universities) and the private sector. Public policy requires this, reflecting a focus on the commercialisation of research through innovation. In this context, finding eminent and relevant academics without links to industry is difficult. Indeed, many of the best scientists in academia now face the dilemma, because of the EU's conflict of interest policy, of choosing between working at the cutting edge of science and undertaking public service;
- At EU-level, many risk management laws now focus on the hazards and risks posed by the use of complex technologies. In some instances, nearly all of the high quality data is generated by companies, much of it protected from competitors by confidentiality agreements. It is essential that the EU institutions have access to the scientists, in business and academia, responsible for generating this data;
- As the EU focuses on risks posed by the use of technologies the likelihood of regulatory failure increases. Many of these risks are already regulated, leaving only the very smallest and most complex. Risk-risk trade-offs are increasingly present. And, understanding the nature of these residual risks requires access to industry-funded science. Conflict of interest policies have to ensure that the EU's institutions have

access to the best available scientific advice, if the benefits of regulation are to justify costs and ensure that new risks are not created.

Possible Ways Forward: The Ideas

- The EU should focus on processes rather than individuals when designing mechanisms for obtaining scientific advice. These processes should seek to be impartial and excellent;
- The processes by which scientific advice is obtained must adapt to the changes that are taking place in the scientific community and the manner in which knowledge is now generated;
- Officials should focus on the quality of scientific evidence and scientific experts;
- EU institutions should cease to focus primarily of financial conflicts-of-interest when selecting scientific experts;
- Selection of experts to participate in advisory processes should reflect a greater understanding, derived from behavioural science, of the nature of bias, of its complex causes;
- Transparency, including disclosure of relevant interests will be essential to build public trust in the management of a wide range of conflicts of interest. Disclosure mechanisms should be designed to enable the widest range of possible conflicts of interest to be identified;
- Declarations of financial interest should be limited to those that are current, and relevant;
- Scientific experts, who meet tests of excellence and relevance, should only be excluded from providing advice in very limited circumstances;
- Scientific committees should aim to manage conflicts of interest rather than to exclude relevant experts;
- Reforms to the design and selection of scientific committees will be more effective if complemented by other changes, including the introduction of standards for scientific evidence, guidance defining the characteristics of the best available science, and peer review of significant scientific assessments;
- The European Institutions should recognise the risks to public trust presented by a system that equates excellence with absence of links to industry and communicate accordingly.

The Huggard Consulting Group
October 2016

Ensuring that Policy-Makers and Regulators Access the Best Quality Scientific Advice

Managing Bias and Conflict of Interest

Part III:

Meeting Agenda

THE HUGGARD CONSULTING GROUP

Ensuring that Policy-Makers and Regulators Access the Best Quality Scientific Advice

Managing Bias and Conflict of Interest (COI)

Monday, October 10, 2016

Chambre de Commerce Luxembourg
7, Rue Alcide de Gasperi
Luxembourg

Good regulation in the European Union depends on the policymaker obtaining top-quality scientific advice on which to base their decisions.

There is a need to safeguard that the quality of scientific advice is not undermined by conflicts of interest (COI).

Conflicts of interest and the potential for resultant bias can also come from a range of non-financial personal reward factors such as power, status and commitments which are difficult to quantify and hence are mostly ignored.

An eminent panel plans to examine the issue of COI and its related bias in a holistic manner by bringing together legal, behavioural, policy, ideological, scientific and journalistic perspectives. It will discuss how the current demands for both excellence and independence/freedom from bias are in conflict and mitigate against getting policy-makers getting the best possible advice.

The event, organised by The Huggard Consulting Group, is designed to stimulate discussion about conflict of interest, how it manifests itself and what might be the recommendations as to how, if it cannot be eliminated, it might be best manage

12.00	Lunch
13.00	Introduction/Opening remarks by Chair – **Aindrias Ó Caoimh :** Former judge of the European Court of Justice
13.10	Keynote speech "The Behavioural Aspects of Bias and Decision-Making"**– Dr Shaul Shalvi:** Center for Research in Experimental Economics and Political Decision-Making at the Psychology Department at the University of Amsterdam (UvA), and Fellow at the Tinbergen Institute
13.50	"How Journalists View Experts and their Opinions" – **Gareth Harding:** Freelance writer, Adjunct Professor of Journalism and Managing Director of Clear Europe
14.05	"Science and Policy in Regulation: The Relationship" – **Prof. Lucas Bergkamp:** Academic/lawyer focusing on the interface of regulation, policy and science
14.20	"Ideology, Campaigns and Conflict of Interest" – **Simon Bryceson MBE:** Senior political advisor and NGO strategist
14.35	"The Scientific Expert's Perspective" – **Prof. Helmut Greim:** Former Scientific Committee Vice-Chairman/ Member
14.50	Break
15.15	Responses in turn by keynote speaker and panellists followed by general panel interaction
15.45	Q&A from floor
16.15	Tour de table of Keynote Speaker and Panellists for observations, conclusions and recommendations
16.45	Chair's summation
17.00	Workshop close and cocktail

Ensuring that Policy-Makers and Regulators Access the Best Quality Scientific Advice

Managing Bias and Conflict of Interest

Part IV:

Thought Piece

THE HUGGARD CONSULTING GROUP

Ensuring that Policy-Makers and Regulators Access the Best Quality Scientific Advice

Managing Bias and Conflict of Interest (COI)

September 2016

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Overview

Good regulation in the European Union depends on the policymaker or, in the case of many science-related issues, the risk manager/regulator obtaining top-quality scientific advice on which to base their decisions. This background paper, drafted in support of the Workshop on "The Quality of Scientific Advice to EU Agencies – *Managing Bias and Conflict of Interest,* sets out to examine the factors and the conflicting demands of excellence and independence/freedom from bias that currently threaten the ability of policy-makers to access the best available expert advice. There is a particular focus on where, and for what reasons, related to the various types of COI, e.g., financial, academic-professional ambitions, power, status, personal commitments and experiences, bias may occur. It will also consider how these are exacerbated by the conflicting demands in the establishment of expert panels. Concluding that simultaneously achieving excellence and freedom from bias is a major challenge, the final section identifies a series of principles for consideration in approaching this, followed by selected observations on the possible options for managing bias as a means of striving for excellence in scientific advice.

Scientific Assessments and Government

Public risk management is one of the fundamental ways in which governments solve problems and meet the expectations of citizens. Although it first came to prominence in the Eighteenth Century, it is today most readily associated with government actions to protect people at work, and to protect citizens and the environment from potential risks posed by technologies and by lifestyle choices.

In managing these risks, scientific evidence has been the key knowledge input for decision-making throughout the "regulatory cycle". Used well, high quality science provides effective ways of identifying potential risks, protecting citizens, stimulating innovation, and using resources wisely. It also enables governments to base actions on evidence derived from open, rational, and predictable processes, enhancing accountability, effectiveness and public trust.

Governments throughout the OECD area have adopted a common approach to utilising scientific evidence to manage the risks posed by technologies and lifestyle choices. Measures are based on expert, systematic assessments of risk, using evidence derived from excellent, leading-edge science, and informed by credible knowledge of real world exposures[1]. In many cases, committees of eminent scientists carry out such assessments.

Thousands of expert scientific assessments are carried out each year, ranging from actions by companies to ensure compliance with product standards through mandatory reviews of regulated technologies by governments to advice on emerging risks provided by committees of eminent scientists. These represent one of the foundation stones on which the legislative and executive functions of modern government rest[2].

Looking forward, demand from the EU's institutions for excellent scientific assessments is likely to increase, as the policy domains for which risk management measures are required expand; as the impact of new technologies becomes more pronounced; and, as the EU implements complex risk management laws

[1] This paper focuses on natural and physical science and engineering because of their importance for understanding and managing risks posed to human health, public safety, and the environment by the production and use of modern technologies.

[2] Scientific assessments are evaluations of a body of scientific or technical knowledge that typically synthesises multiple factual inputs, data, models, assumptions and/or best professional judgements to bridge uncertainties in the available information. These assessments include, but are not limited to state-of-science reports; technology assessments; weight-of-evidence analyses; meta-analyses; health, safety, or ecological risk assessments; toxicological characterisations of substances; integrated assessment models; hazard determinations; or exposure assessments. (Source: derived from a definition used by the US Office of Management and Budget, 2004)

designed to restrict the potential harms posed by the use of complex, modern technologies.

Clearly, the technical input and advice that the policy-makers receive is only one consideration in developing policy (Digital Education Resource Archive, 1999). However, policy that is based on advice that is of poor quality or is the subject of bias runs a great risk of producing an adverse outcome for the citizens of Europe.

Regulatory Effectiveness, Public Trust and Scientific Assessments

Since the mid-1990s, policy-makers have set out to improve the quality of regulatory decision-making. Reflecting initiatives taken by the OECD (OECD, 1995, 2012, 2015). New methods of decision-making have been adopted to improve regulatory effectiveness whilst, at the same time, strengthening confidence and trust in government institutions. In the light of these reforms, policy-makers frequently require scientific assessments to be both "excellent" and "independent". Access to the best available science ensures that assessments are excellent, with greater acceptance of the findings of such scientific assessments and the regulatory measures they guide, if these are perceived to be independent. Here, independence is seen as a surrogate for being impartial and bias-free. At EU-level this is a formal requirement and is, for example, reflected in the Rules of Procedure (Scientific Committees, 2009, 2013) adopted by the EU's independent scientific committees.

Delivering an effective trade-off between these goals is, however, difficult to achieve in practice as it raises two fundamental questions. How can it be made certain that the policy-makers get advice from the experts with the best experience and knowledge, drawing on the best available science (Excellence)? What steps need to be taken to ensure that this advice is as free from bias as possible (Independence)?

All too often, the requirements of "excellence" and "independence" are deemed to be satisfied, if evidence, and related assessments, is supplied solely by academia and ideally by those with no funding links to the private sector.

There are major problems with this traditional approach in relation to excellence.

In the first place, it is based on out-dated assumptions about the nature and funding of academic research and the focus of public risk management measures. As such, it also fails to recognise the importance of the private sector in the R&D process and that the modern focus of many risk management laws is on the performance and use of technologies. This is the area where scientific progress takes place primarily through investments in knowledge by industry. RAND (Rand, 2009), an academic research institute, identified this problem in an evaluation for the European Commission. This "excellence gap", the evaluators suggested, was most pronounced in areas of applied research, where expertise lies predominantly with the private sector.

A second problem, is excessive focus on the provenance or the funding of the science used in assessments. Over 85% of all R&D activity in the EU involves funding by business or, reflecting the goals of government innovation policies, partnerships between the private sector and research institutes or universities. In some areas of scientific research, particularly those that are new, nearly all of the knowledge is generated through processes that involve the private sector. A further aspect of this is that many top academics are engaged with industry on projects related to new and innovative products and processes, in relation to which confidentiality agreements have been signed. Thus, the need to disclose all projects with industry as part of declarations of interest (European Commission C(2016) 3301 final) creates yet a further barrier to participating in committees providing expert advice.

Considering the independence aspect a further problem arises.

In the selection of "independent" experts for provision of scientific advice to regulators and

policy-makers, there is pressure to focus almost exclusively on financial conflicts of interest. This strong focus on financial COI is also the case when it comes to publication of articles in many learned journals, for example, the declarations required by the International Society of Addiction Journal Editors (ISAJE website). These risk stigmatising (Gmel, 2010 and Peele, 2010) anyone who, in the past, has engaged with industry. This ultimately leads to those who can make a real contribution avoiding involvement because of the likelihood of *ad hominem* attacks (Tierney, 2010).

Bias and Conflict of Interest – A Multi-Faceted Issue

Biased behaviour is seen as developing when a wide variety of personal reward factors including financial, academic or professional ambitions, power, status, personal commitments and experiences (Babor, 2014 and Young, 2009) come into conflict with an individual's professional obligations.

It is now generally agreed that there is a strong behavioural dimension to the manner in which bias develops. This breaks with the traditional view that bias is a rational or "economic account" (Moore, Tanlu and Bazerman, 2010) process which involves the weighing of the pros and cons of taking a given decision. The conclusion arrived at by academics who adhere to the rational choice perspective, together with the media, much of the public and those that seek to deliver *ad hominem* attacks is that it is a matter of "deliberate corruption" (Moore and Loewenstein, 2004). The current view (Moore, Tanlu and Bazerman, 2010 and Thagard, 2007) is that judgement and decision-making is much more complex and involves "automatic" and "controlled" processes which act in concert. This research has been even taken further into examining why people lie (Verschuere and Shalvi, 2014), collaborate in unethical behaviour (Weisel and Shalvi, 2015) and seek to justify it (Shalvi et al., 2015).

Research (Thagard, 2007) has suggested that the automatic process component takes place in the parts of the brain (the amygdala and the nucleus accumbens) which are associated with emotional reactions, processing of memory, decision making, fear and impulsivity. On the other hand, the controlled element is associated with the neocortex, where higher functions such as spatial reasoning, conscious thought and sensory perception take place.

In certain, predicable situations, these two processes come into conflict, with the automatic ones frequently acting in relation to self-interest and the controlled processes being the drivers for professional responsibilities. While the automatic processes tend to be fast, effortless, involuntary and not accessible to introspection, the controlled processes are slow, effortful, voluntary and accessible to introspection (Moore and Loewenstein, 2004). The potential for dominance of the automatic element of this dual processing is further enhanced by a number of dimensions that are present in many conflict of interest situations. For example, when likely victims are a remote and diffuse group, they are less likely to provoke a visceral reaction similar to that produced by potential victims that are known to the decision-maker, e.g., specific clients or colleagues.

This research does not seek to excuse the adverse outcomes of bias, but rather to explain that bias is frequently not the product of a rational choice as it is most often portrayed. It also offers insights as to why bias not only results from financial conflicts of interest but can just as easily come from a variety of other drivers including academic or professional ambitions, power, status, allegiances, personal commitments and experiences.

The Impact of Transparency on Bias

The current drive for transparency has placed those providing advice in a veritable fishbowl with little room for "space to think". Experts are aware that policy-makers need not just to have the best possible scientific advice available, but also need to take account or address the impact on of citizens directly affected. This brings additional pressure on the experts (Michaels,

Holmes and Shaxson, 2014) as they are acutely aware of the interests of other stakeholders when making decisions involving scientific substance, particularly if these interests are being advocated strongly.

An additional dimension is that the complexity of regulation is increasing while at the same time policy-makers and politicians are increasingly reticent to be seen as taking unpopular decisions. These factors have combined such that decisions, which involve the balancing of values of various societal groups, the true responsibility of politicians, are simply being avoided. Rather, these have been delegated to technical and scientific committees, the members of which are then faced with taking political decisions that have been positioned as scientific ones. A prime example of this was in the REACh chemicals legislation (Regulation (EC) No 1907/2006) which incorporated the catch-all, value laden phrase "substances of equivalent concern".

The Need to Take a Holistic View

The European Commission, via the rules of procedure (Scientific Committees, 2009, 2013) acknowledges the potential sources of COI and the attendant biases in its Declaration of Interest (DOI) and associated guidelines (European Commission C(2016) 3301 final). However, it does not address these issues comprehensively, electing simply to ask if there is any other relevant information or if the expert has taken public positions or defended interests in the field in question. Similarly, the European Ombudsman's own initiative report (European Ombudsman, OI/6/2014/NF), while worthwhile, similarly does not propose how bias resulting from all forms of COI might be addressed. Rather it stresses the concept of "perception of conflict of interest" and speaks to the need for public acceptance by addressing the media and communications dimensions. This is seen as necessary because the media will admit (Tierney, 2010) that it is easier to focus on financial COI and thus appeal to the public (Hine, Peele and Philp, 2012) compared to other, more complex factors. However, society is poorly served if biased advice, or advice that is simply wrong, is allowed to be disseminated even if this is done because the provenance is perceived as being acceptable or to avoid media criticism.

Bias and COI in Learned Journals

Conflict of interest and the potential for resultant bias is currently a high profile issue in relation to scientific advice to regulators and policy-makers. However, as noted above, for some considerable length of time, it has also been an issue for the editors of the learned journals on which the expert committees' members rely. There has been work (DeAngelis and Fontanarosa, 2008) which relates industry support for research with bias in publications. In the past, the peer review process has been promoted as the manner in which errors, biases and other potential faults could be identified. However, the effectiveness of the peer review process and the attendant quality and accuracy of publications has been called into question. This is attributed to the increasing volume of publications and the belief that progress in science means the continual production of positive results (Sarewitz, 2012). This is exacerbated by the paucity of experienced reviewers overlaid with any inherent biases they may have.

Addressing the Issues

Simultaneously achieving excellence and freedom from bias is a major challenge. The following section identifies a set of principles for consideration in approaching this. This is followed by the selected observations of a range of experts on the possible options for managing bias.

Principles for consideration:

- Formal policies for carrying out scientific assessments to focus primarily on ensuring "excellence". To ensure this, all relevant scientific experts who meet agreed standards of eminence, excellence, and relevance are eligible for selection. This includes scientists

from other geographic areas and those employed by, or working with, stakeholders.
- Within an overall policy framework, scientific assessments are required to meet agreed standards of "impartiality". "Impartiality" is achieved through the working methods of the committees, as well as through the selection of scientific assessors.
- Through a transparent selection process that uses peer group nomination and self-identification, experts are chosen who meet agreed standards of excellence and who are able to act objectively and in the public interest.
- Selection processes are transparent and take due account of and distinguish clearly between all major causes of bias, recognising that each creates different challenges for "impartiality". These are disclosed fully.
- Scientists are excluded if they have current direct financial interest or if knowledge gained could create competitive advantage or if their ideological or emotional biases are likely to prevent them from acting objectively. This final problem is deemed to occur if an expert is totally committed to a particular point of view and unwilling, or reasonably perceived to be unwilling, to consider other perspectives or relevant evidence to the contrary (US National Academy of Science, 2003).
- Policies recognise the importance of basing all assessments on the best available science, including that funded by stakeholders. Transparent processes for achieving this are put in place.
- Before the findings of a significant scientific assessment are made public they are subject to a formal peer review. This examines both the process carried out and the substance of the findings of the assessment.

Managing Bias

In seeking to address the issue of bias that results from the various types of conflict of interest, a number of suggestions have been made and a number of proposals critiqued (Sarewitz, 2012, Thagard, 2007, Tierney, 2010). Some of these are directed at journals but may be adapted for the purposes of scientific advice. In any event, the issue of scientific advice, bias and conflict of interest does not exist in a vacuum.

In a general context, it was suggested (Sarewitz, 2012) that universities and journals should endeavour to reduce the hype related to special projects. However, he recognised that this would be difficult to achieve when set in the context of these institutions trying to attract funding and the benediction of government on activities that promote cooperation.

One proposal (Tierney, 2010) was that each scientist should list all the public and private donors on their web pages and journalists "could simply link to that page and let readers decide for themselves".

Another option, originally targeted at journals, which may have applicability in the context of scientific committees, is that the role of all authors is clearly indicated in terms of the research and writing of the manuscript. In a committee context, the roles of the rapporteur and the reviewers on the committee and the members investing significant time in the report drafting (in addition to the rapporteur) or reviewing the report, could be reported.

A structured review (Thagard, 2007) of five possible options to eliminate or reduce bad decisions resulting from COI, covered *pure reason, disclosure, complete avoidance, social oversight and neuropsychological information*. For *pure reason*, a process whereby decisions are based on optimal reasoning patterns, it was concluded that expecting people to disconnect their emotional systems when making important decisions was unrealistic. On *disclosure*, benefits were seen but it was deemed impossible for those to whom the conflict of interest is disclosed to fully evaluate the extent to which the decision is influenced, or not, by the COI. When the option of *complete*

avoidance was examined, the major problems were seen as the risk of losing the best people and that non-traditional COIs are difficult to identify. The strategy of *social oversight*, a process which suggests that the peers of the decision-maker may be able to identify errors to which the agent is oblivious was considered. While it was acknowledged that those providing oversight may well bring their own biases to this type of review, it did hold some promise, particularly if combined with transparency. The final option of *neuropsychological information* involves educating people more about how cognition and related emotions are intimately connected and how inaccessible to conscious introspection these connections are. The view taken was that people thus informed would be less confident of the basis and validity of their decisions, leading to greater scrutiny. The conclusion was that taken together, these five options had the potential to reduce the incidence of bad decisions resulting from conflict of interest.

Closing Discussion

Unless the traditional approach is reformed, the quality of regulatory decision-making will deteriorate with significant implications for governance, prosperity, and protection from risk. If scientific assessments fail to be perceived as impartial then confidence in public institutions is eroded and there is less acceptance by citizens of risk management measures, including those designed to manage risks posed by lifestyle choices. If assessments, and the evidence on which they are based, fail to meet widely-accepted standards of excellence, then the likelihood of regulatory failure increases, reducing protection from risk, creating unintended negative consequences, and, in some instances triggering additional risks (risk-risk). Prosperity is threatened too. Regulatory decisions based on poor quality scientific assessments erode incentives to innovate because they create unpredictability and, all too often, divert resources into the defence of existing technologies rather than in exploiting new ideas. Taken together, regulatory failure and poor governance standards undermine legitimacy.

Finally, one journalist (Tierney, 2010) an outspoken critic of all types of influences, advocates to "follow the science, not the money".

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September 2016

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