FUTURE DIRECTIONS FOR SCIENTIFIC ADVICE IN EUROPE

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BIOMEDICINE AND THE LIFE SCIENCES: CORE ISSUES FOR SCIENCE-BASED POLICY ADVICE

Jörg Hacker, **Stefan Artmann** and **Sandra Kumm**

In democratic and pluralistic knowledge societies, science-based policy advice fulfils three functions. First, it provides political decision-makers with state-of-the-art scientific knowledge that is reliable, relevant to societal concerns and transparent with respect to uncertainties. Second, science advice can systematically analyse policy options for the solution of societal challenges and evaluate them in the light of given objectives. Third, it contributes to public debate on policy goals and objectives by probing the rationality underlying differing normative ideals and concepts of common welfare.[1]

There are as many topics for science-based policy advice as there are public problems that can be analysed by scientific methods – including societal challenges caused by developments in science and technology. During the last forty years, the tremendous progress in biomedicine and the life sciences has been one of the core issues of science-based policy advice and it is, in our view, a good bet that this will not change in the foreseeable future. Biomedicine and the life sciences present a special class of public policy issues, but they can be understood as a test case that illustrates some of the opportunities and challenges for future directions of scientific advice in Europe.

Biomedicine and the life sciences are revolutionising our understanding of life and health

We are all concerned about our bodily integrity and health. More or less consciously, any human being evaluates her or his corporeal abilities against some standard of wellbeing that varies according to many cultural, social and individual factors. This comparative evaluation almost always influences, with a strong normative force, decisions about how to lead one's life.[2] It is therefore understandable that we nourish high hopes – and foster

deeply engrained worries – about any research that has the potential to expand, for good or bad, the power to control our bodily functions and to change our conceptions of health.

Since the 1940s research into the molecular foundations of living systems has been advancing our understanding of the nature of life and the clinical abilities of physicians at an ever-accelerating pace. Examples of this progress are abounding; we will just mention some of the topics that have been considered by the German National Academy of Sciences Leopoldina and the European Academies' Science Advisory Council (EASAC) in the last few years. These topics include the efforts to combat infections that can pass between animals and humans, the impact of climate change on infections, the challenges facing antibiotics research, and the European public health policy for infectious diseases. Statements have been published on predictive genetic diagnostics as an instrument of disease prevention, and on the effects of a limited legal approval in Germany of pre-implantation genetic diagnosis. Challenges and opportunities for taxonomy (a discipline with a long history) and for synthetic biology (a promising new field of research) were analysed. Scenarios for the future development of high-throughput ('omics') technologies in Germany have also been developed.[3]

Any reader of the statements published by EASAC and the European national science academies will surely conclude that not only do biomedicine and the life sciences involve many of the most promising research programmes of our time, they are also revolutionising the art of medicine – and thereby transforming human self-understanding.

In constitutional democracies, citizens who are interested in, or concerned about, the consequences of biomedicine and the life sciences can freely speak out for or against public policies on scientific research, technological innovation and healthcare. This usually results in a broad spectrum of opinions – e.g. on the regulation of stem cell research – that are discussed in the public sphere and taken into consideration in political decision-making. This pluralism of legitimate interests voicing their diverse views is a fundamental characteristic of democracies, and pertains also to normative (juridical and moral) dimensions of public policies on science, technology and health.[4] In open societies, these interests are part and parcel of the bargaining processes at the end of which decisions about public policies are made.

A well-functioning science policy advice system can help supply state-of-the-art information on those high-impact sciences. Cool-headed advice is needed on options for dealing with hotly debated issues, and critical competence is required in scrutinising goals and objectives of public policies on ethically challenging issues. Science-based policy advice can make a strong contribution to fulfilling those needs.

Enhancing evaluation, cooperation and the appreciation of values

Reflecting on the experience of the Leopoldina in contributing advice on biomedical policy, two general aims have emerged. The first is to offer scientific advice to help evaluate distinct policy options to achieve an agreed goal. The second – perhaps more fundamental – is to help provide a forum and vocabulary to enable different value positions to be articulated and to explore room for compromise.

The first type of these aims can be applied to any kind of allocation problem; given an agreed policy goal, it is necessary to determine the optimal use of different kinds of resources in terms of costs and benefits. A good example comes from giving advice on antibiotic resistance. There is a broad agreement on the principal goals of public policy on antibiotics: the spread of antibiotic resistances must be reduced and new antibiotics have to be developed. The general means to reach these goals are also relatively uncontroversial: more research is needed, the transfer of scientific discoveries into clinical application must happen more smoothly, and the proper use of antibiotics by physicians and the general public should be encouraged. But it is a great challenge to advise on how the human, institutional, financial and other resources of science, innovation and public health systems should be optimised in order to stop the spread of antibiotic resistances and to develop new antibiotics. Not only does this involve questions of funding and organising science, from basic research to clinical studies; it also implies legal frameworks (e.g. the certification conditions for new active agents), social aspects (e.g. health education on the sensible use of antibiotics) and economic factors (e.g. tax incentives for research and development).

In 2013, the Academy of Sciences and Humanities Hamburg and the Leopoldina published a statement, *Antibiotics Research. Problems*

and Perspectives,[5] that proposed a scientific agenda and made eight concrete recommendations, ranging from strengthening basic research and facilitating clinical research, to restricting the use of antibiotics in veterinary medicine and consistently implementing antibiotic consumption records, to intensifying socio-economic research and establishing a national round table on antibiotics research. In their statement, the Academies emphasise that:

> *"The concerns of antibiotic resistance and the lack of antibiotics can only be resolved or at least alleviated if the policymakers in the fields of science, politics, society and industry decide to cooperate and act on a national and international level to pursue a variety of concerted efforts."*[6]

Following this example, a general aim of science-based policy advice on allocation problems should be to enhance cooperation between all stakeholders in order to optimise the use of resources for public policies on research and health. The two main instruments to reach that aim are communicating to stakeholders the best available scientific information about what we know and what could be done, as well as evaluating, against given policy goals, the options for action as impartially as possible.

Negotiation of compromises and the appreciation of values

The second type of aim for science-based policy advice covers any sort of value conflict; given the need to define policy goals, it is necessary to support the negotiation of compromises in the appreciation of values needed for the definition of public policies.

A good example of such a value conflict is pre-implantation genetic diagnosis (PGD). PGD is a diagnostic procedure that allows parents at high risk of having a child with a hereditary disease to have a child unaffected by the disease. The procedure involves examining in vitro fertilised embryos for the presence of particular genetic changes indicating hereditary diseases. In Germany, an intense public debate on PGD arose in 2010 after the Federal Court of Justice had delivered a judgment that a ban on PGD could not be derived from the Act on Embryo Protection.

In 2011, the Leopoldina, together with the German Academy of Science and Engineering (acatech) and the Berlin Brandenburg Academy of Sciences

and Humanities (BBAW), published an ad hoc statement *Preimplantation Genetic Diagnosis (PGD). The Effects of Limited Approval in Germany*,[7] which recommended that PGD should be placed on an equal legal footing with prenatal diagnosis, and that the German legislative should vote for a limited approval of PGD. The statement covered not only medical but also juridical and moral aspects of the issue, and summarised its normative conclusions as follows:

> *"If it is assumed that avoiding having a child cannot be demanded by the state under any circumstances, then legally approved embryo selection by a woman within the context of a limited approval of PGD may contribute to the avoidance of terminations of pregnancies, including late terminations. Furthermore, unaffected in vitro embryos could then be 'saved', since they could, with the consent of the woman, be transferred. As a result, limited approval of PGD would mean that the procedure would no longer be associated with the inevitable death of unaffected embryos. At the same time, the dignity of the woman would not be violated since she could make the decision herself in accordance with her own conscience. Even if the dictates of her conscience do not concur with the moral or religious views of others, the fact still remains that respecting the conscience of individual persons and accepting moral beliefs, but not stipulating these attitudes in a legal sense so as to render them generally binding, is a characteristic of a free democratic constitutional state. Should specific morally binding attitudes exist, a decision based upon conscience would preclude the performance of PGD."*[8]

This citation concisely exemplifies the general goal of science-based policy advice on value conflicts, which are amongst the hardest problems in the context of biomedicine and the life sciences. The aim of the advisers should be to develop strategies of fair bargaining between all stakeholders in order to support the negotiation of compromises in the appreciation of values. Such compromises allow the involved parties to define the goals of public policies on research and health as consentaneously as possible. Against the background of the best available scientific information about what we know and what could be done, the most useful method of science-based policy advice for the development of fair bargaining strategies is to reconstruct and to analyse – as impartially as possible and as sympathetically as necessary – the actual principles that connect the value preferences, the policy evaluations and the political actions of each stakeholder.

Scenario-building to help guide advice on policy options

Science-based policy advice in constitutional democracies ought to respect the division of labour between politically responsible decision-makers and advisers who want to help find reasonable ways of defining and implementing public policies. Winston Churchill reportedly once said, *"Scientists should be on tap, but not on top"*.[9] 'Expertocracy' or technocracy must, therefore, not be a future direction for science-based advice – even if we currently observe a trend, particularly when it comes to the contribution of science to sustainable development, to blur the distinction between advice and decision.[10] In democratic societies such a trend would lead to an erosion of legitimacy for political decisions as well as to a loss of trust in the impartiality of science-based advice.

If we want to draw a clear demarcation line between advising and deciding, it is best to think about science-based policy advice as suggested by the Hungarian-American economist and 1994 Nobel Prize winner, John C. Harsanyi, in respect to ethics – *"in terms of hypothetical imperatives"*,[11] i.e. in terms of propositions of the general form 'If you want X, do Y'.

Thinking in terms of hypothetical imperatives about the optimal allocation of resources, given certain policy goals, means to develop and apply techniques for cost–benefit analyses of public policy. How to model the probable effects of alternative science policies and how to study empirically the real effects of implemented science policies – both questions are an essential part of the task that the presidium of the Leopoldina described in its 2013 discussion paper *The Sustainability of the German Science System. Supporting the Future Development of Research, Teaching and Knowledge Transfer*, as follows:

> *"The societal impacts of science, the growth of knowledge and its substantive and institutional differentiation present science with significant challenges that can only be surmounted when its relationships to other areas of society are examined using the methods of scientific enquiry, thus allowing a more substantiated approach to the management of these relationships."*[12]

Recently, a Leopoldina working group on the challenges presented by omics technologies for Germany's infrastructures in research and teaching used the technique of scenario-building to handle complex questions of

science policymaking.[13] Harnessing the full potential of high-throughput technologies for scientific and medical ends requires, above all, the massive introduction of new training programmes for young scientists, the fast development of a nationwide IT infrastructure, and the goal-oriented cooperation of universities and non-university research institutions. The working group developed two scenarios for the establishment of a national omics and IT infrastructure as a network of distributed, topically-focused omics centres. These scenarios specify some main characteristics of that infrastructure – namely access, financing, linkage to European and international infrastructures, and training and career possibilities.

We know, of course, that the comparison between two scenarios for the development of research infrastructures is just a first step in advising on complex planning issues in science policy. Yet it seems to us that it is a promising step, going in one of the directions that should be taken by science-based policy advice on biomedicine and the life sciences in the future.

Practising the role of the impartially sympathetic adviser

New research programmes in biomedicine and the life sciences usually do not raise only questions of the optimal allocation of resources; first and foremost, they have a high potential to pose problems in the appreciation of values. An example is synthetic biology, the merger of biology, chemistry and engineering that further develops genetic engineering and biotechnology in order to purposefully modify existing living systems or to construct new ones from scratch. Synthetic biology is quite a young research programme that will, to our mind, become an even more important topic for science-based policy advice in the near future.

Together with the German Research Foundation (DFG) and acatech, the Leopoldina published a statement on synthetic biology in 2009, which has been adapted to the European level by EASAC.[14] The first-mentioned statement explicitly addresses the necessity of a systematic appreciation of values as regards synthetic biology:

> *Moral arguments in favour of producing artificial life are based on the anticipated benefits for medicine, agriculture, energy generation or the environment, thus making the exploitation of synthetic biology not only permissible but even advisable. Although synthetic biology is justified by the economic advantages and ultimately by the freedom of research, according to the general consensus it should, however, be subject to other basic rights such as the right to physical integrity."*[15]

The public debate about what goals public policies on synthetic biology should pursue will not lead to a consensus between all stakeholders. Neither is it a legitimate aim of political decision-making in constitutional democracies to suppress moral pluralism. Nor is it necessary for science-based policy advisers to wait for unanimity about normative questions before they begin their work; they can start with a task that Harsanyi has, mutatis mutandis, described as follows:

> *If two codes of behaviour are equally self-consistent, the choice between them is not a matter of logic alone, but rather primarily a matter of personal attitudes. However, analysis by moral philosophy of alternative codes of behaviour can help us to make our choice more intelligent."*[16]

Some future directions for science-based advice in biomedicine and the life sciences

"Making a choice more intelligent" should mean taking into account the internal consistency as well as the consequences of different normative systems when choosing between them. If stakeholders with different moral standards are involved in making political decisions about science and health policies, the best science-based policy advice can reasonably hope to do in making those decisions more intelligent is to develop bargaining strategies between the stakeholders that raise the probability of achieving a compromise, e.g. regarding the regulation of synthetic biology by law. The science-based policy adviser thus becomes a good host, or an impartially sympathetic referee in *"a properly managed debate with understandable and reliable communications that addresses the challenges of synthetic biology"*.[17] We are suggesting that any step towards such an ambitious, yet realistic, understanding of the role of the scientist as an adviser is a step in the right direction for science-based policy advice – in Europe and elsewhere.

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Endnotes

1. See Hacker, J. and Artmann, S. (2014) Vom Nutzen wissenschaftlicher Neugier für die Demokratie – Die Rolle der deutschen Wissenschaftsakademien. In Thies, E. and Leibinger-Kammüller, N. (Eds.) 'Politik für Wissenschaft und Forschung in Deutschland.' Düsseldorf: Droste. pp. 13–27. See also Hacker, J. and Artmann, S. (2015) Über die 'harten Fakten' hinaus: Ethische Implikationen der wissenschaftsbasierten Beratung von Politik und Öffentlichkeit, to be published in Albrecht, C. (Ed.) 'Ethik und wissenschaftliche Politikberatung.' (TTN-Studien Band 4) Baden-Baden: Nomos.
2. An influential and much-debated analysis of the existential role and normative character of conceptions of health was made by the French physician and philosopher Georges Canguilhem in his 1943 'Essai sur quelques problèmes concernant le normal et le pathologique' (expanded 1966 edition translated as 'The Normal and the Pathological' by Fawcett, C.R. and Cohen, R.S. New York: Zone Books, 1991).
3. The statements of Leopoldina and EASAC are available at http://www.leopoldina.org/en/home/ and http://www.easac.eu/ respectively (last accessed 7 October 2014).
4. The constitutive role of pluralism in liberal democracies is one of the main topics of modern political philosophy. See, for example, Rawls, J. (1993) 'Political Liberalism'; expanded edition New York, NY: Columbia University Press, 2005.
5. See Academy of Sciences and Humanities Hamburg and German National Academy of Sciences Leopoldina (2013) 'Antibiotics Research. Problems and Perspectives.' Hamburg: Academy, and Halle (Saale): Leopoldina. pp. 49.
6. Academy Hamburg and Leopoldina (2013) p. 15.
7. See Leopoldina, acatech and BBAW (2011) 'Preimplantation Genetic Diagnosis (PGD). The Effects of Limited Approval in Germany.' Halle (Saale): Leopoldina.
8. Leopoldina, acatech and BBAW (2011) p. 3.
9. Cited by Randolph Churchill (1965) 'Twenty-One Years.' London: Weidenfeld and Nicolson. p. 127
10. For an incisive criticism of that trend, see Strohschneider, P. (2014) Zur Politik der Transformativen Wissenschaft. In Brodocz, A. et al. (Eds.) 'Die Verfassung des Politischen. Festschrift für Hans Vorländer.' Wiesbaden: Springer VS. pp. 175–192.
11. See Harsanyi, J.C. (1958) Ethics in Terms of Hypothetical Imperatives. In 'Mind' N.S. 67 (1958), pp. 305–316.
12. Leopoldina (2013) 'The Sustainability of the German Science System. Supporting the Future Development of Research, Teaching and Knowledge Transfer.' Halle (Saale): Leopoldina. p. 6.
13. See Leopoldina (2014) 'Report on Tomorrow's Science. Life Sciences in Transition – Challenges of Omics Technologies for Germany's Infrastructures in Research and Teaching.' Halle (Saale): Leopoldina.
14. See DFG, acatech and Leopoldina (2009) 'Synthetic Biology. Positions.' Weinheim: Wiley-VHC and EASAC (2010) 'Realizing European Potential in Synthetic Biology. Scientific Opportunities and Good Governance.' Halle (Saale): Leopoldina.
15. DFG, acatech and Leopoldina (2009) p. 87.
16. Harsanyi, J.C. (1958) p. 315.
17. DFG, acatech and Leopoldina (2009) p. 87. And see also p. 86 on 'a platform for structured discussions' about ethical issues.