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PROCEEDINGS

PROGRAMME AND TABLE OF CONTENTS

LINK TO THE VIDEO OF THE CONFERENCE
http://www.coe.int/en/web/bioethics/conference-videos

Opening

Ms Gabriella Battaini-Dragoni
Deputy Secretary General of the Council of Europe

Ladies and gentlemen,

So many of our greatest achievements have technology at their heart – and nowhere more so than in the biomedical field.

We live longer and healthier lives than any generation before us. Previously untreatable conditions can now be kept under control.
In genetics and other fields, we find ourselves on the brink of breath-taking new discoveries.

And it is always right that, as we advance our knowledge, we remain alive to the social and moral questions which so often accompany progress of this kind.

More than 5 centuries ago, Rabelais declared that 'Science without conscience is but the ruin of the soul.'

And, for several decades now, the Council of Europe has sought to be part of that conscience.

Our Convention on Human Rights and Biomedicine – produced in 1997 – was the first ever international treaty to bring these two things together: biomedicine and human rights.

It was a milestone in putting the autonomy and the consent of individuals, in particular, at the centre of the application of new discoveries and developments.

The Convention created protections for individuals who for whatever reason – age, mental state – might not be able to make informed choices. And it continues to serve as a hugely important tool.

And the Council of Europe continues to take our responsibilities in this area very seriously. We understand the liberating power of technology, and equally we are the guardian of human rights.

I want to thank the Belgian Chairmanship of the Council of Europe's Committee of Ministers for supporting this Conference – it is extremely timely.

As our technologies become more complex and interlinked, so do the questions they pose for liberty and human dignity.

Nanodevices inserted into the body, for example, can help identify cancer cells at a very early stage, allowing us to refine treatments and improve monitoring. That is a wonderful thing.

But, here there is a link to information and communication technology. Suddenly it becomes possible – from these tiny devices and the records they create – to collect huge amounts of sensitive personal data. What does that mean for privacy? For data protection? For the right to know and not to know?

Neurodevices, such as brain implants, help us treat conditions like Parkinson's disease and clinical depression, which for so long were regarded as incurable. But they may also modify and influence behaviour, thereby challenging human autonomy and integrity.

We are also increasingly seeing technologies, which were initially developed in health, subsequently applied in other fields.
Today, for example, neurotechnology developed to record brain activity for biomedical reasons, is also proposed for gaming, therefore falling outside of the safeguards developed in the medical domain.

So, in many ways, the lines are blurring: between medical and non-medical domains; between private and public spheres; between clinical and research fields.

It is no surprise, therefore, that in recent years our Court – the European Court of Human Rights – has at times found itself grappling with human rights questions flowing from developments in biomedicine.

Our Parliamentary Assembly has also done very important work on this space, with regard to nanotechnologies – technologies which might appear in our clothes or toiletries or cosmetics, but for which there has been little public debate on the side effects and risks.

And I am sure that this conference will make a hugely important contribution too.

The aim today is to identify the big priorities for human rights in relation to bioethics - *as the basis for action*.

I am delighted to see so many fields and interests represented here: scientists and medical professionals, specialists in human rights, lawyers, sociologists, philosophers, economists, representatives of patients' associations, the private sector and academia.

All of your voices and perspectives will be crucial if we are going to preserve the energy and dynamism of technological innovation, while simultaneously safeguarding human rights.

So thank you for being here. I wish you the best for your day.

Opening

Ms. Liliane Maury Pasquier, Member of the Council of States (Switzerland)

Chair of the Sub-Committee on Public Health of the Parliamentary Assembly of the Council of Europe

Madam Deputy Secretary General,
Ambassador,
Members of the Bioethics Committee,
Ladies and Gentlemen,

I would like to begin by quoting a war veteran[1], who, on witnessing the horror of the Normandy landings, said:

> "If we continue to develop our technology without wisdom or prudence, our servant may prove to be our executioner".

I think that these words sum up perfectly the reasons why we are meeting here today.

We are here today because we know, from experience, that technological developments can lead to the most spectacular progress and to economic and social development as well as help to improve human rights. Indeed if we now live longer and in better health, it is thanks to the progress made in science and technology.

Unfortunately, however, past experience has also taught us that technological progress can also have devastating consequences and pose a threat to the whole of humanity if it is not properly controlled or not used wisely.

The atomic bomb is a case in point but we can also take a theoretical example which is more relevant to today's discussions, that of deep brain stimulation.

Indeed, we know that this technique can be used to treat certain symptoms associated with Parkinson's disease. This is a major breakthrough for tens of thousands of patients suffering from the disease, and we know that Parkinson's is likely to affect an increasing number of people in the coming years.

But imagine what would happen if the same technology were used to influence and change the behaviour of individuals, to the point of depriving them of their free will. What would happen if it were used for military purposes or to enslave nations? What would the consequences be? The idea is terrifying, don't you think?

In order to identify the challenges which emerging technologies pose to human rights, it is essential that we take into consideration the way in which these technologies are used and the aims pursued.
Another equally important element is that of the unpredictable or uncertain nature of the potential effects of new technologies. The fact is that we do not know whether their use entails risks and, if so, the extent of such risks for the simple reason that we do not have sufficient hindsight.

To illustrate this, I would like to take the example of nanotechnologies given that the Parliamentary Assembly recently looked into this issue in one of its Recommendations[2].

As you know, nanomaterial is already being mass-produced and is incorporated into everyday consumer products such as suntan lotion and cosmetics, food packaging, clothes etc. However, we

[1] General Omar Bradley, an American veteran of the Second World War.
[2] Recommendation 2017 (2013) Nanotechnology: balancing benefits and risks to public health and the environment"

have as yet no idea of the long term consequences of this use of nanomaterial for human health and the environment

So should we just sit back, wait and see, and hope that everything will turn out for the best? Or should we apply the precautionary principle of avoiding any possible and considerable damage and perhaps irreversible effects?

For years, the response of the Parliamentary Assembly and the Committee of Ministers of the Council of Europe to this question has been that the precautionary principle should be incorporated into scientific and technological processes with all due respect for freedom of research and innovation. In 2005 in the Final Declaration of the 3rd Council of Europe Summit, the Heads of State and Government of the Council of Europe undertook to "guarantee the security of their citizens while fully upholding human rights and fundamental freedoms" and in this context to meet "the challenges attendant on scientific and technical progress".

Governments therefore need to control the potential risks of new technologies without undermining technological, economic and social dynamism. However, regulations often have difficulty in keeping abreast of scientific innovations and the legislative framework in force tends either to act as a brake on innovation or to be inadequate when it comes to controlling risks. The Council of Europe should assist states in the complex process of striking a balance between innovation and human rights.

Today's conference is a first step in this direction. We shall endeavour to identify the main challenges to human rights posed by emerging technologies. In this context, we shall look at not only essential issues such as autonomy, integrity and individual privacy but also questions of form such as accessibility and governance.

But I don't think we can afford to leave it at that. This kind of debate should not be the preserve of specialists. The challenges inherent in scientific or technological progress should be the subject of real democratic debate as recommended in Article 28 of the Oviedo Convention, for these issues concern each and every one of us and society as a whole. I am therefore very pleased that the conclusions of this conference will serve as a basis for a White Paper, which will, I hope, be made public and lead to a broad debate not only among the eminent experts but also among the wider public.

Ladies and Gentlemen,

I would like to conclude by expressing a wish. I have noticed that most science-fiction films present a version of the future where progress has overtaken our humanity and the values we hold today. A world where human beings are cloned and in which clones are used solely for the purpose of producing replacement organs for their "genitors"[3], or a world where eugenics are practised on a vast scale[4]. What I would like to see is a world where technological progress is driven by values and not the other way round. It is our responsibility vis-à-vis future generations; we owe them that much!

I wish you all a very successful conference and thank you for your attention.

[3] "The Island".
[4] Welcome to Gattaca.

Session 1 - Introduction
Driving force for developments

Prof. Andy Stirling (United Kingdom)

Science Policy Research Unit, University of Sussex

Abstract

This paper will review some key features of the dynamics driving the emergence of new technologies. It will highlight how the challenges presented for social justice do not simply concern the pace of change and associated risks and distributional impacts. Dynamics of lock-in, mean there are also profound questions over the directions taken by emerging technologies in particular sectors.

This raises challenges around the 'opening up' of research and innovation – and recognising the crucial roles for social movements and civil society. In short, challenges for social justice presented by emerging technologies are not just about distributions of risks and benefits around particular privileged trajectories. They are about democratising the directions of progress itself.

Driving Forces in Emerging Technologies: issues of social justice and democracy in innovation governance

Full background paper based on various earlier work, including a chapter at pp.49-62 in the 2014 Annual Report of the UK Government Chief Scientific Adviser.

Emerging technologies present many opportunities and challenges to governance of human rights in the broadest of senses. These considerations extend far beyond conventionally recognised – albeit crucial – issues inherent in the distribution of associated benefits, impacts and uncertainties. A human rights lens invokes issues far beyond safety, extending into diverse notions of social wellbeing and human flourishing. And realities of uncertainty, ambiguity and intractability mean conventional regulatory tools like risk assessment are entirely inadequate.

Likewise, ethical issues cannot satisfactorily be addressed simply by focusing on modalities for implementing the particular privileged emerging technology trajectory favoured by the most powerful proximate interests. Processes of emergence mean that new technologies reproduce and reinforce particular existing formative cultural and political structures and are co-produced with other novel encompassing social orders. In short, ethical consideration around human rights implications of emerging technologies are intrinsically political. The fundamental questions are therefore over choice between contending institutional pathways – social, organisational and cultural as well as technological.

Here, issues of equity of possibility and equality of outcome arise as much in the directions taken by these pathways as in the detailed modalities of implementation for any one. Perhaps most crucial in human rights terms, is that it is those social groups that are already most politically marginalised (therefore most vulnerable in other ways), for whom the stakes tend to be highest. Excluded groups typically stand to lose most both in respect of endured impacts and foregone opportunities of alternative pathways of emergence that might more effectively address their own needs and aspirations.

In these and other respects, then, emerging technologies emphasise a general predicament in the application of ethical approaches to the governance of human rights. Just as science itself is unable to deliver single definitive prescriptions to determine self-evidently preferable courses of action, so too is this true of any (among many possible) ethical frameworks. Here as elsewhere, ethics is about deep, broad and balanced deliberation over the implications of contrasting understandings, values and moral norms. So, ethical responses to human rights imperatives will inevitably be plural and conditional in nature.

As such, it is as true of the ethics of human rights, as of other aspects of emerging technology governance, that the main issues transcend narrow policy debates and instruments, to implicate wider political discourse and interests more broadly. As important as the particular ethical principles and approaches that might be highlighted, then, are the democratic qualities of the arenas within which these are discussed and addressed.

The reasons for this are readily explained. Emerging technologies are not a particular category of technology, but a relational process implicating all technologies and their encompassing innovation dynamics in the broadest of senses. And innovation itself is about much more than technological invention. It involves change of many kinds: cultural, organisational and behavioural as well as technological. And there are no guarantees that any particular realised innovation will necessarily be positive. Just as innovation is not a one-track race to the future, so too is this even more true of broader processes of emergence. So, ethical governance of emerging technologies is not so much about optimizing a single trajectory, as it is a collaborative process for exploring diverse pathways. In order to realise the enormous progressive potential of particular orientations for emergence, what are needed are more realistic, rational and vibrant forms of 'innovation democracy'.

Yet arguably the greatest obstacle to this, is that conventional innovation policy and regulation tend simply to assume that whatever products or technologies are most energetically advanced, are in some way self-evidently beneficial. Bioethics approaches do little to alter this basic structure, focusing disproportionately on the modalities of implementation for the most privileged trajectory of emergence. Scrutiny tends only to be through narrow forms of quantitative 'risk assessment' – often addressing innovation pathways at a time too late for significant change. Attention is directed only in circumscribed ways at the *pace* of innovation and whether risks are 'tolerable'. The result is a serious neglect for the crucial issue of the *direction* of innovation in any given area – and increased vulnerability to various kinds of 'lock in'.

These patterns show up across all sectors and forms of emerging technology. Beyond GM crops, for example, there exist many other innovations for improving global food sustainability. But the relatively low potential for commercial benefits often leave many promising options seriously neglected. And this 'closing down' of innovation is intensified by deliberate exercise of powerful interests at the earliest stages. For instance, official statistics often conceal the extent to which patterns of support are concentrated in favour of particular innovation pathways. And where uncertainties are side-lined, even scientific evidence itself can carry the imprint of vested interests. Yet these effects of power remain unacknowledged in policy making. Policy is stated simply as 'pro-innovation' – a self-evident technical (rather than political) matter.

To address these challenges, the governance of emerging technologies should extend beyond conventional innovation policy, to more explicitly and transparently acknowledge the inherently political nature of the interests and motivations driving contending pathways. Here, this paper explores the potential for three emerging bodies of practice, relevant across all areas: participation, responsibility and precaution. Each involves a range of practical methods and new institutions. Precaution in particular is a subject of much misunderstanding and mischief. Among other qualities, this offers a

crucial guard against the error of treating the absence of evidence of harm as evidence of absence of harm – and highlights the importance of wider human and environmental values.

Together, qualities of participation, responsibility and precaution extend scrutiny beyond anticipated consequences alone, to also interrogate the driving purposes of innovation. They allow societies to exercise agency not only over the rate and riskiness of emerging technologies, but also over their directions. And they offer means to enable hitherto more distributed and marginal forms of innovation – which presently manage only rarely (like renewable energy or ecological farming) to struggle to major global scale. Together, these qualities celebrate that the ethics of emerging technologies are – like innovation more generally – not a matter of fear-driven technical imperatives, but of a democratic politics of contending hopes.

1. The Breadth and Diversity of Innovation

Innovation is not just about technological inventions. It encompasses all the many ways of furthering human wellbeing. This includes improved production and use of goods or services in firms and other organisations [1]. But it also includes new practices and relations in communities, households and the workplace [2]. Advanced science and technological research can help drive and enable innovation [3]. Yet many other new forms of knowledge and action are also important [4]. Innovation can be created and guided by social venturing [5] and mobilisation [5] as much as commercial entrepreneurialism [6]. So grassroots movements [7], civil society [8], creative arts [9], and wider culture [10] feature alongside small business, service industries [11] and the public sector [12] in being as important for innovation as universities, research labs and high-tech companies.

Of course, there are no guarantees that any particular innovation in any of these areas will necessarily be positive. To take extreme examples that most may agree on, new forms of torture [13], financial fraud [14] or weapons of mass destruction [15,16,17,18,19,20] are all active areas for innovation that might be judged to be generally negative. For other kinds of innovation, the picture is varyingly ambiguous. But it is rare that any given innovation is entirely, unconditionally or self-evidently positive [21]. And judgements are always relative. So, the unqualified claim in the current British Government slogan – "*innovation is Great… Britain*" [22] – is not automatically true. Like other prevailing high-level talk of 'pro-innovation' policy — for instance, around the European Union's 'Innovation Union' strategy [23,24,25] — this misses the crucial point that the most important queries are about 'which innovation?'. Whether or not any given innovation is preferable on balance to alternatives – let alone unreservedly 'good', still less "*great*" – is not just a technical issue. It is also a fundamentally political question. This means that even quite detailed aspects of innovation policy are legitimate matters for democracy [26–32].

In these widest of senses, however, well-conceived innovations can undoubtedly offer important aids not only to economic productivity [33], but also to enhancing many kinds of human flourishing or the public good [34]. And this need not be a bone of contention, even under the most critical views [35]. The more ambitious the aspirations to progressive social change, the greater the need for broad, diverse (and carefully scrutinised) kinds of innovation [36] [37]. An example lies in the imperatives for transformations towards a more Sustainable [38], equitable, healthy and peaceful world. Whatever forms these possible futures are held to take, they require radical kinds of innovation in the widest of senses [39].

Some innovation opportunities can be effectively addressed by well-governed fair and efficient markets [40]. So, one important role for innovation policy lies in helping to foster commercial innovation in the public interest [41]. But not all benefits, risks or impacts are restricted to those private actors typically most directly involved in steering business innovation [42]. Established understandings, motivations and incentives driving the most powerful market actors, often fail fully to prioritise wider relevant social values and interests [43]. In areas like health, agriculture, energy, environment, water, mobility, security, waste and housing, many of the least privileged (most vulnerable) people around the world are disproportionately excluded from conventional global patterns of innovation [44]. Nor (as we shall see below) are many important forms of uncertainty and ambiguity always fully or appropriately addressed by relatively narrow market-based signals or official statistics [45].

Depending on the context, then, market processes alone do not necessarily drive the best orientations for the kinds of innovation that are most needed from broader social viewpoints. This is true both across different domains of policy as well as within any given sector. For instance, the single largest

area for public expenditure on research and innovation – in the UK as worldwide – is military [46] [47]. Innovation towards less violent means for conflict resolution are relatively neglected [48] [49] [50]. Likewise, the most strongly-pursued energy options are those that offer greatest returns on established infrastructures and supply chains, rather than new distributed forms of renewable power or energy services [51] [52] [53] [54]. For it's part, biomedical research tends to focus more on health disorders of the rich than the poor, and on therapeutics rather than prevention [55]. This is especially so in speculative (but potentially lucrative) new areas like 'human enhancement' and 'life extension' [56] [57] [58], with the Royal Society raising particular questions about patterns of prioritisation in neuroscience [59]. Consequently, there are important roles for public policy in helping to prioritise across sectors, as well as encourage and support appropriate scales and directions for innovation within particular areas. And (as we shall see later), public policy is also crucial in helping to address the many uncertainties and ambiguities – by promoting greater analysis, deliberation and political accountability [60].

In nurturing these qualities, public policy can also fulfil other significant roles. Alongside higher education, business and civil society, government policy can do much to promote the knowledges, capabilities and environments that best facilitate socially effective innovation [61]. So, the more demanding the challenges for innovation (like poverty, ill health or environmental damage), the greater becomes the importance of effective policy [62] [63]. These challenges of innovation policy go well beyond simplistic notions of governments trying to "pick winners" [64] [65]. In any case, imperfect or self-serving foresight does not exclusively afflict the public sector, but also applies to powerful market actors [66]. Though manifest differently, essentially similar degrees of uncertainty, intractability and deficiency are equally experienced in government, business and civil society [67]. Instead then, the central challenge in innovation policy is about helping to harness the differences [68]. This is about culturing the most fruitfully cross-fertilising conditions across society as a whole, for collectively seeding and selecting across many alternative possibilities and together nurturing the most potentially fruitful [39]. This involves collaboratively deliberating, negotiating and constructing what 'winning' even means, not just how best to achieve it. These are the questions on which this paper will focus.

2. Policy and the Politics of Choice

The most important (but neglected [69]) issue here, is that innovation of all kinds in any given area is not a one-track race to the future [70]. Instead, it is about social choices across a variety of continually branching alternative pathways for change [71]. In this sense, innovation is more like an evolutionary process than a race [72] [73]. It is as much about exploring a space of different possibilities, as optimising any one [74–76]. As already mentioned, it is rarely self-evident – and often hotly contested – what should count as the most 'desirable' directions for discovery. This is true, for instance, of particular domains like Sustainable agriculture, zero carbon energy services or clinical and preventive responses to improving public health. In all these areas, there unfold many radically contrasting alternative pathways for innovation. Two of the most pervasively important qualities in choosing which pathways to prioritise, are therefore: *(i)* attending fairly to a ***diversity*** of possible directions and strategies [77]; and *(ii)* including a ***plurality*** of perspectives in appraising any one [78–80].

Consequently, it is not only important that innovation be efficient and competitive in any particular direction. It is also crucial equally for economic and wider social wellbeing, that the directions that are prioritised for innovation, are as robustly deliberated, accountable and legitimate as possible [81]. An economy that fails to do this, exposes itself to the risk that it will become committed to inferior innovation pathways, that other more responsibly and responsively steered economies may avoid. In other words, innovation may "go forward" quickly, but in the wrong directions.

History presents plenty of examples of innovation trajectories that later proved to be misguided – for instance involving asbestos, benzene, thalidomide, dioxins, lead in petrol, tobacco, many pesticides, mercury, chlorine and endocrine-disrupting compounds, as well as chlorofluorocarbons, high sulphur fuels and fossil fuels in general [82,83]. In all these and many other cases, delayed recognition of adverse effects incurred not only serious environmental or health impacts, but massive expense and reductions in competitiveness for firms and economies persisting in the wrong path [84] [85]. Innovations reinforcing fossil fuel energy strategies [65] – like hydraulic fracturing [86] – arguably offer a contemporary prospective example. And similar dilemmas are presented by the otherwise exciting new possibilities of nanotechnology [87] – both internally within this field and externally with respect to alternative ways to address the same priority social needs [88].

The key conundrum here, is that each alternative innovation pathway in any given area (like food, energy, health or security), will typically display contrasting pros and cons under contending perspectives. Animated differences emerge, for instance, around infrastructures for urban automobiles or cycling [89], nuclear power or renewable energy [66] and violent or peaceful approaches to national security [50] [49]. Each involves different innovation trajectories. Competing pathways will also routinely differ in their social distributions of benefits and harms, winners and losers. And – in any view – the whole picture is further obscured by many deep unknowns. Crucially, a decision *not* to innovate will also present its own mix of pros, cons and uncertainties. Innovating in any particular direction will – for instance, through foregone resources and opportunity costs – typically diminish innovation in others. Whether deliberate or inadvertent, each direction for innovation is a social choice – involving issues of uncertainty, legitimacy and accountability as well as competitiveness.

It is important to acknowledge these complexities of choice, because innovation debates in particular areas often become quite simplistic and polarised. For instance, innovation in fields like food, health, energy or warfare is frequently discussed as if it were a one-track race [70], rather than an exploratory process – simply about whether to '*go forward*' or not. But the crucial questions in such areas are typically not just about '*yes or no?'*, '*how fast?*' or '*who's winning?*'. What often matters more instead, are queries over '*which way?*', '*what alternatives?*', '*who says?*' and '*why?*' [90]. And the scope for uncertainties under these wider questions, compound the scope for controversy. So, conflicts can become especially intensive and disabling (and potentially economically disastrous), if these broader questions are ignored.

Across all fields, the key challenge is that there exists no single definitive 'sound scientific' or 'evidence based' way to calculate the most rational balance of resources to expend on alternative innovation pathways within or across different domains [91]. A robust knowledge base and rigorous analysis are both necessary. But these are typically insufficient. The merit rankings constructed for different innovation choices by expert analysis invariably overlap – and may often be inverted – under contrasting equally reasonable assumptions and value judgements [92] [93] [94] [95] [96]. Decisions concerning which kinds (or areas or aims) of innovation to prioritise are therefore inherently partly subjective, rather than purely technical or economic. This is why research and innovation remain intrinsically political matters, irrespective of whether or not they are acknowledged to be so.

This makes it all the more important that high quality information concerning public policy in and around innovation, is available for wider scrutiny and debate. But the recent House of Lords Select Committee on Science and Technology report on the setting of priorities for publicly funded research, identified several important areas for improvement [97]. The Committee confirmed that there remains important scope for enhancing the quality of official UK statistics concerning public support for contrasting innovation pathways. It made recommendations that this information be clarified in several particular ways. Yet these recommendations remain to be implemented. Consequently, further deliberate efforts are required in order to enable more transparent and accountable democratic politics concerning the directions and rationales underlying UK innovation policy.

3. Steering Innovation Pathways

One reason why it is important to address the politics of choice in innovation, is that chosen pathways can quickly become effectively irreversible. A diversity of well understood social, political and economic processes exert various kinds of positive feedback as innovation pathways unfold. These can act to reinforce the trajectories favoured by the most powerful interests, and exclude others that may be more widely beneficial.

Typically, it takes a lot of effort for people, organisations and markets to learn about any new way of doing things, capitalise on the opportunities and adapt to the changed requirements. As these efforts become 'sunk investments' in a particular innovation, they can help reinforce commitments to the associated pathway. This can occur, even if the innovation in question is widely seen to be unsatisfactory [98]. Although complicated [99], a classic example of this remains the QWERTY keyboard [100,101]. This was originally designed for nineteenth century mechanical typewriters, specifically to adjust typing in order to reduce jamming of the type bars for letters frequently used together. But this very property of modulating typing speed, helps aggravate office injuries [102]. There exist better keyboard configurations [103]. Yet the deeply socially embedded familiarity of QWERTY makes it difficult for alternatives to become established. So, the problem persists through successive innovations in

electronic typewriters, computers and touchscreen tablets, continuing several technological generations after the initial rationale lapsed. Even where the incumbent innovation is essentially a product of historical chance, then – with no powerful backing – it can prove very difficult to reverse the associated path dependency.

This dynamic of path dependency makes it especially important to do whatever is achievable at the earliest stages of innovation, to give confidence that unfolding directions are as appropriate as possible [104]. The dilemma is, of course, that this is precisely the time when the positive and negative implications are most uncertain [105,106]. So, there can be enormous pressures on all sides, to exaggerate the confidence with which evidence can be interpreted and to understate the scope for competing interpretations [107]. One reasonable response to this, is to be much more open and questioning about uncertainties [91]. Another rational measure, is to extend scrutiny beyond anticipated consequences and also look at the driving purposes of innovation [108]. Whilst the variously claimed positive, negative and indirect effects may remain uncertain, the motivating values, interests and incentives that lie behind particular innovation pathways are typically much clearer [109]. In this way, critical appraisal of the driving forces behind alternative innovation pathways (not just the claimed aims) can be undertaken with confidence at an early stage, despite the uncertainties [110].

This kind of careful broad-based societal consideration is, however, rarely evident in mainstream innovation. More often, it is a narrower range of expectations about the future that most strongly drive directions for change. The values upheld by particular communities of researchers themselves may be influential, as well the interests of leading firms, powerful financiers or particular users [111]. If a specific pathway is strongly held to be more likely than others by these kinds of influential actors, then this can become self-fulfilling [112]. Examples include competing media formats or software operating systems, where early market penetration can be driven more strongly by expectations about future adoption, than by assessments of performance [73]. Some degree of performance shortfall is often the price for collective compatibility [113]. Consequently, expectations can add to path dependencies mentioned above, compounding the 'locking in' of a particular innovation, and the 'crowding out' of alternatives [114]. This is an issue that arises, for instance, in the case of nanotechnology [58].

Processes of learning, volume production and economies of scale can add to these positive feedbacks. For instance, 'lock in' can be significantly further reinforced by measures to standardise infrastructures [115], establish organisational momentum [116], appropriate intellectual property [117 118], build monopolies [119], realise rent on value chains [120], condition user preferences through marketing [121], 'capture' regulators [122] and 'entrap' competing political interests [123]. The overall result of such so-called 'network externalities', are a range of powerful 'increasing returns' that can entrench a particular favoured trajectory and exclude other paths [124]. Despite being ignored in the apparently simple policy language of '*going forward*', these more complex dynamics in science and innovation do not go unnoticed by interests wishing variously to reinforce (or disrupt) particular pathways [125 126]. So, if innovation policy is to be fair and effective, it is therefore important that it attends to these processes in explicit, direct and accountable ways.

These challenges are formidable enough. But, as indicated above, problems of 'lock in' are intensified where important roles are also played by the deliberate exercise of powerful interests at the earliest stages of an innovation process, in order intentionally to promote particular favoured pathways or disadvantage others [127 128]. For instance, automobile manufacturers and allied industries sought historically to promote the car by suppressing competing urban public transport systems [129]. Likewise, lead compounds were promoted as anti-knocking agents in transport fuels, at the expense of less profitable alcohol-based products, even though these were very early known to be less harmful [82]. A further example of this more deliberate type of lock-in includes the strategies of the tobacco industry over the past century to maintain high levels of consumption [130]. Before it was finally abandoned in most countries, the nuclear fuel reprocessing industry also worked for many decades actively to engineer continuing government support [123]. And now, ostensibly disinterested debates over alternative radioactive waste management strategies also inherently depend on – and help condition – future prospects for new nuclear power [131,132]. Most recently, pharmaceutical industry strategies have been challenged for neglecting innovation of medically vital antimicrobials due to their low profitability [133]. Where innovation systems are driven by these kinds of dynamics, there are especially important roles for democratically responsive government policy and collaborative international pressure.

It is crucial not to misunderstand the implications of 'lock in'. In order to be successfully achieved, even the most positive innovation pathway will require some closing down in associated standards, regulations and practices [134]. So 'lock in' in some sense, is not in itself necessarily a bad thing. But it remains a significant policy dilemma, since it means that not all potentially good innovations that are technically practicable, economically feasible or socially viable will actually prove to be historically realisable. The most important point then, is that these issues need to be discussed and addressed openly – and democratically – rather than brushed under the carpet or drowned in simplistic and polarising 'pro' claims (or 'anti' accusations) over innovation in general.

4. Opening Up Innovation Portfolios

Many of the above examples are retrospective – judged with the benefit of hindsight. Looking forward in any given area, it becomes even more difficult to conclude definitively which of a variety of innovation pathways offers the most favourable balance of pros and cons. One especially important prospective example lies in the field of innovation for more Sustainable global food systems [135]. How will a growing world population be fed at a time when natural environments are increasingly stressed [136]? Here there exists a particularly rich diversity of possible innovation pathways, each with contrasting implications [137]. Many kinds of diversity are possible [138]. But public debates display a shared tendency on all sides to close down discussions as if about just being 'for' or 'against' the single family of innovations around 'genetic modification' (GM), favoured by the most powerful interests in this sector.

With resulting policy debates polarised by this especially deep form of power play [139] [140], it is often portrayed as if GM were – self-evidently and in-principle – either individually indispensable or uniquely unacceptable. Whatever reasonable political perspectives are taken on the pros and cons of the many disparate innovation pathways in this field, neither of these positions is actually tenable. In fact, the much-discussed (apparently specific) innovation of 'GM plant breeding' is much more complex and ambiguous than often suggested by either critics or advocates alike. Apparently technical variations like 'transgenics', 'cisgenics', 'apomixis', 'gene editing', 'genomic assist' and 'marker selection' [141] each offer partly overlapping and partly contrasting benefits and risks – and present important differences in their potential social, political, economic and ecological implications [142].

For example, among the more striking recent claims made for UK Government supported research towards enhanced Sustainability in global staple crops, are the remarkable flood tolerance qualities reported for 'scuba rice' [143]. But these have been achieved through 'marker assisted backcrossing', rather than any form of transgenics [144]. So, the most important factor typically differentiating "GM" technologies is not that they offer a unique means to secure crop improvement. The crucial distinction lies more often in the potential for innovating firms to recoup investments by obtaining rents on intellectual property or global supply and value chains [145]. For instance, transgenic crops are often deliberately engineered for tolerance to particular proprietary broad spectrum herbicides, thus expanding their sales [146]. Or the inclusion of particular transgenes can make the resulting organisms patentable, and thus more reliable sources of royalties [147]. It is the resulting forces and counterforces that help make the ensuing discussions so regrettably polarised.

This point becomes even more important as attention extends beyond science-intensive innovations. Outside the techniques of molecular genetics, there are many other promising innovations for improving global food sustainability [137]. These include participatory breeding [148], agricultural extension services [149] and open source seed sharing methods [150], which harness the innovative capacities of farmers themselves and help tailor crop development to important local conditions [151]. Likewise, there exist many innovations in wider agricultural practices that also offer significant benefits to the productivity of small farmers [152], including intercropping [153], integrated pest management [154] and other methods of ecological farming [155] and Sustainable agriculture [156].

Likewise organisational innovations in the food chain also offer potentially major benefits, including reforms to distribution systems, storage provision and better food waste management [157]. Arguably the greatest implications for equitable global food availability, however, are presented by innovations that are still wider in scope [158], including reforms to land tenure and agricultural property rights [148], income support for marginal famers [159], social equality between different rural groups [160], or moving diets towards lower meat consumption [137]. These kinds of innovation may often offer significantly greater benefits to poor farmers, consumers or communities than science-intensive technological solutions.

But their less attractive commercial benefits mean they remain, like Cinderella, too often uninvited to the innovation party.

What is shown by this food sector example, is that – even in a specific area – innovation is not about simply '*forging ahead*', '*lagging behind*' or '*catching up*' [161]. It is not a single-track race driven by a particular privileged field of science. Instead, it is about diversity, exploration and choice. This is why it is misleading to uphold particular pathways as offering exclusively '*sound scientific*', definitively '*evidence based*' or uniquely '*pro innovation*' options (…or for all contingently-emerging innovation to be asserted necessarily to be "great"). And this is why exaggerated '*no alternatives*' language (on any side) can polarise controversy and so also impede effective innovation policy. By seeking to invoke the general authority of science and technology in partisan ways, this kind of language does not only threaten effective innovation. It also risks compromising science and undermining democracy itself [162]. More mature and rational debate recognises that choosing between the pros and cons of alternative innovation pathways like those exemplified here, are less technical than they are political.

A more reasonable and productive way to handle these crucial issues in innovation policy is to be more transparent, deliberate and accountable about when it is right to 'open up' and when to 'close down' in any particular field [163]. This means that no particular innovation should be unduly favoured by policy making, simply because of its appeal to particular powerful vested interests within a given innovation system. Nor should it be treated on these grounds as self-evidently existentially unacceptable. Either position requires context and perspective -specific argument. In other words, what is needed is mature political debate, as much as ostensibly definitive analysis [164]. What can be recognised as well, though, are the benefits of some requisite degree of diversity [165]. And (as we shall see), this is a general quality that can be achieved in many different ways – also potentially excluding any particular innovation.

This can be illustrated by the further example of the challenge of mitigating climate change by building zero carbon energy infrastructures. Here decades of intensive research by government and industry bodies has shown that there exist (despite the formidable constraints) a range of alternative innovation pathways that are viable under contrasting equally-informed understandings [166]. For some, the solutions centre around nuclear power [167]. Others highlight large scale use of carbon capture and storage [168]. In the wings, momentum is growing behind expedient and idealised aspirations somehow deliberately to control the global climate through 'geoengineering' [169–173] – a technology threatening particularly acute and irreversible forms of 'lock in' [174 175]. Yet all the time (albeit not backed by such powerful interests), a rich array of renewable energy technologies is available for addressing climate change in a diversity of radically different distributed or centralised ways [176–179].

The crucial point is, that there is no definitive technical or economic reason why any of the above energy strategies cannot (for better or worse) provide a basis for a variety of zero carbon UK or global energy futures. Crucially, this includes the clear feasibility (equally for the UK and Europe [180 181 182 179 183 184] and the world as a whole [166 185 118 119]) of energy strategies built entirely around efficiency and renewables. Yet one of the main obstacles to this, lies in high profile self-fulfilling assertions to the contrary – including by authoritative policy figures [188 189]. In energy as in the food sector discussed above, then, the obstacles to less favoured strategies are typically more commercial, institutional and cultural than they are technical. Amongst the most potent of these political obstructions are claims from partisan interests – like incumbent nuclear or fossil fuel industries – that there exists 'no alternative' to their favoured innovations and policies [188]. Even given the formidable constraints bearing on sustainable energy and agriculture then [190], there remains much hidden scope for radical choice. This is a matter for critical democratic deliberation as much as technical analysis [39].

There are many ways to resist such unhelpful syndromes and to develop more reasonable debates about innovation. These will be returned to below. Some are about the style of discourse – developing a greater tolerance on all sides, for embracing adverse public reactions to particular innovations. When they transcend privileged 'not in my backyard' parochialisms, general public preferences offer an important guide to the general orienting of innovation [191]. Just as scepticism is one of the crucial constituting qualities in science itself [192 193], so space for healthy critical debate and public dissent can help improve the quality of innovation more generally [194 195]. With mainstream institutions often especially strongly disciplined by incumbent powerful interests, the role of delivering on this important quality of scepticism often falls disproportionately to civil society [196].

And this crucial role of social movements and wider civil society extends beyond debate and controversy. It is remarkable how many presently major global industries are building around once-marginal technologies like wind turbines, ecological farming, super energy-efficient buildings, or green chemistry [7]. All of these owe key elements in their pioneering origins to early development by grassroots social movements [197]. For instance, without the small country of Denmark remaining partly 'below the radar' of international nuclear interests, able to nurture alternative energy strategies in the 1970s driven strongly by anti-nuclear social movements, it is arguable that the present multinational wind industry might never have become competitive [198]. This is just one of the examples of innovations that were systematically marginalised – sometimes actively suppressed – by incumbent interests in science, government and industry [199].

It is of course important not to become too romantic about the dynamics of social movements and their favoured innovations [196]. These too warrant exactly the same kinds of healthy scepticism appropriate to other actors in innovation debates. But history does make clear where it is that many of the ostensibly driving environmental and social justice concerns come from, that currently play such prominent roles in the justification of innovation policy. Without decades of struggle by social movements dedicated to humanitarianism, environmentalism and social justice, it is doubtful that high level global agenda-setting developments like the Stockholm Environment Conference or the Brundtland Commission or the Millenium Development Goals would ever have become as formative as they are now in shaping the general climate of global governance – or innovation debates in particular [200–203 204,205 206]. Here, the same basic pattern is arguably reproduced, as in the crucial roles played by social movements in other emancipatory transformations around colonialism, slavery, women's and gay rights [207 208 209,210].

Just as the famous astronomical missing mass stabilises the visible structures of galaxies, so these apparently intangible distributed social forces help condition the gradients that ultimately help forge and steer new directions for innovation [211]. The greater the critical interest in the most progressive orientations for innovation – rather than those that preserve the status quo – the more this is generally true.

5. Risk, Uncertainty, Ambiguity and Ignorance

As has been mentioned, these policy making challenges are compounded, because the pros and cons of different innovation pathways are – under all views – subject to seriously incomplete knowledge. The normal way to address these dilemmas, is by means of regulatory risk assessment [212 213 214]. Although often not implemented in full, this prevailing approach invokes the apparent authority of probabilistic analysis [215 216 217] to assert a notionally single 'sound scientific' or 'evidence-based' picture [218 219 220 221]. This task can be approached in many variously complex ways [222 223 224]. But at root, it involves alternative possible positive and negative outcomes being weighted by their respective perceived likelihoods to derive a single overall 'expected value' for the balance of future benefits and harms [225 216].

In conventional innovation policy and regulation then, it is simply assumed that whatever products or technologies are most energetically advanced for assessment of risk, are in some way self-evidently beneficial [226 227]. Questions then typically focus on whether any associated risks will be 'tolerable' [228 229 230]. It is rare for the claimed benefits themselves to be rigorously scrutinised [231], let alone compared in a balanced way with other potential benefits of alternative innovation pathways [232 83]. So, existing forms of risk regulation do little to address the wider issues in innovation politics discussed above.

Further challenges arise in the reliance of risk-based regulation on the methods provided by probability theory [233 234]. Probabilistic tools can be useful in tackling familiar, high-frequency, relatively unchanging challenges, as found (for instance) in risk regulation of many urban transport or public health systems [235 236]. Where empirical evidence arising in past experience is held to be a reliable guide to the future, these tools can be very powerful – as in established responses to familiar safety risks [237]. But where an innovation pathway (or its context) is novel, complex or rapidly changing, uncertainties cannot confidently be reduced to single definite probabilities [238]. Such inabilities to justify a single picture of probabilities can arise, for instance, in the regulation of nanotechnologies [239], endocrine disrupting chemicals [240], or novel living organisms [241]. Under these conditions, it can be irrational to assert a single definitive 'evidence based' picture [242]. In these fields (as more widely), policy making must often contend with contrasting – but equally reasonable – interpretations of

uncertainty [107] [91]. These cannot reliably or rationally be reduced to simple single numbers for probabilities.

These are not the only limits to risk assessment. Beyond uncertainty in the above sense [243] [244] [245], there exists a further array of challenges [246] [247]. These involve not the relative likelihoods of different outcomes, but the meanings of the possibilities themselves. For instance, divergent views may exist over how to categorise or partition different kinds of benefit or harm. Or there may be major questions over how to frame the various dimensions under which these are defined [248]. What are the appropriate imaginations, understandings, values, or interests according to which they should be interpreted or prioritised [249]? There may also be differences over which innovation pathways to include or exclude from scrutiny, or how to allocate attention [105].

These are challenges of ambiguity, rather than strict uncertainty [250]. Here, the problem is not so much about uncertainty, as contradictory certainties [251]. And risk assessment is no more able fully to resolve these disagreements over meanings as over likelihoods [252]. Indeed, Nobel Prizes have been awarded in rational choice theory, for axiomatic proofs demonstrating there can be no definitive way to guarantee the calculation of a particular optimum balance between contending ways to interpret, measure or prioritise possible outcomes [253] [254] [255]. Yet such challenges remain not only the norm in many innovation debates, but constitute the key issues in contention in controversies like those over alternative agricultural, energy or health strategies [256]. Under ambiguity, claims to single definitive 'sound scientific' or 'evidence-based' prescriptions are not only seriously misleading, they are an oxymoron [257].

The above difficulties may seem tricky enough. But even more intractable than uncertainty and ambiguity, is the further challenge of ignorance [258] [106] [246] [259]. Here possibilities are not just disagreed about, but at least some are entirely unexpected [247] [260]. This was the case, for instance, in the early regulatory history of bovine spongiform encephalopathy (BSE) [261], endocrine disrupting chemicals [262] and damage by CFCs to stratospheric ozone [263]. Like many other cases [82,83], these involved mechanisms that were not just thought unlikely at the inception of the issue, but were at the time 'unknown unknowns' [264]. Where we don't know what we don't know [265] the prospect is raised of possible 'black swans' [266]. These challenges are not about calculable risk, but inherently unquantifiable surprises [267,268]. Here again, to seek to assign single definite values for 'risk' are not just irrational but dangerous [269].

Of course, surprise is not necessarily always a bad thing. It is intrinsic to the rationale for 'blue skies' science – as well as research and innovation more generally – that positive benefits can also be entirely unexpected [267]. An example might be the laser – a novel laboratory phenomenon that was for a long time a 'tool' without a use [270]. Likewise (albeit involving many variously questionable applications), the internet has also undoubtedly given rise to a host of positive benefits that were initially entirely unexpected [271]. But it is also clear – for instance in areas like nanotechnology [272] – that there is no guarantee that further research will necessarily reduce uncertainty, ambiguity or ignorance [273]. As Einstein famously observed, it is often the case that the more we learn, the more we find we don't know [274]. And, of course, this is not necessarily bad. Indeed, it is a key motivation in science [275]. It is political pressures that resist the humility of acknowledging ignorance [276].

Either way, it is clear that some of the greatest dilemmas in innovation governance extend well beyond risk – they are about surprises. With conventional regulatory risk assessment entirely unable to deal with this deepest form of incertitude, the importance of robust critical deliberation and wider political argument about innovation, is seriously reinforced.

6. Precaution and Diversity

One widely established and intensely debated response to these challenges in innovation policy, is the precautionary principle [277] [278] [279] . Although it comes in many forms [280], a classic general expression of precaution, is that scientific uncertainty is not a reason for inaction in preventing serious damage to human health or the environment [281]. By explicitly hinging on uncertainty rather than risk, precaution helps promote recognition that social choices in innovation are not reducible to ostensibly precise, value-free, technical risk assessments [282]. These dilemmas are instead explicitly recognised to involve wider issues and alternatives requiring overtly value-based – and so 'political' in this sense – deliberations over policy.

This message is inconvenient to many partisan perspectives wishing to dragoon the authority of science as a whole in favour of specific interests [283]. Often driven by such motives, opposition to precaution rests largely on assertions (or assumptions) that established 'science based' regulatory risk assessment offers a sufficient general response to the challenges of social choices across alternative innovation pathways – and a particular way to justify favoured technologies [284 285]. So, precaution remains a subject of much misunderstanding and mischief [286 287 288 289]. This often involves ironically emotive rhetoric in supposed defence of reason [219]. It is on these grounds, for instance, that arguments are sometimes made that it is somehow irrational not to always use probabilities to qualify potential hazards [290]. In this way, many critics of precaution mistakenly ignore uncertainty, ambiguity and ignorance, insisting instead that these be treated as if they were risk [225]. The precautionary principle has played a crucial role in fostering more rational reflection about these highly political pressures on the use and abuse of science in technology regulation.

Treating general dilemmas of uncertainty, ambiguity and ignorance as a simple state of risk, perpetrates the misunderstandings discussed above – that probabilistic analysis is universally applicable and that innovation is a single-track race. When these misapprehensions are corrected, precaution can be recognised simply as a guide to the more reasonable and realistic steering of social choice among possible innovation pathways [291]. So precaution is not (as often alleged) about being somehow generally 'anti-innovation' or 'anti-science' [292 293 219]. Instead, it simply urges greater rational consideration of different aspects of incertitude than can reasonably be reduced merely to risk [83,264,269,294,295].

Consequently, precaution does not automatically mean abandoning any particular innovation, still less innovation in general [296]. Contrary to many claims [297], there is nothing inherent in the precautionary principle that automatically requires bans [298], or makes it partisan in its applicability to innovations of contrasting provenance [299 300]. Precautionary action inhibiting any one innovation pathway, inevitably favours another [294]. And precaution does not even mean abandoning risk assessment [237,301]. It simply reminds that risk-based approaches do not offer a complete response to deeper challenges of choice.

Precaution is also a guard against the error of treating absence of evidence of harm as evidence of absence of harm [302]. This is often a particular danger for innovations whose novelty means there has been little time for evidence to accumulate, or where incumbent interests discourage research or assessment of the requisite kinds [303]. Before invoking a lack of evidence of harm, it is necessary to think about how visible this evidence might actually be expected to be if it existed – or how vigorously it is sought [304]. Identifying false negatives is often more important than avoiding false positives [82]. In this respect, precaution is a guard against wilful and misleading blinkers favouring incumbent interests and the inertia of the status quo [305].

In essence, precaution simply highlights that innovation policy and associated politics should pay more careful attention to the intrinsically problematic nature of knowledge – and its vulnerability to economic and political pressures. But it does not just highlight problems. The precautionary principle also opens the door to solutions – pointing to a range of rigorous and practical strategies and practices for dealing with the realities of uncertainty, ambiguity and ignorance in innovation [83 269 282 306 307 308 309 310 311]. These 'Cinderella methods' can be neglected, where there persist preoccupations solely with deterministic notions of 'risk', 'exposure' and 'vulnerability' (rather than 'uncertainty','ambiguity' and 'ignorance') – and a consequent sense that risk assessment alone is sufficient [269]. Practical examples include a range of different tools for 'opening up' regulatory appraisal [312], research strategies [313] and innovation policy [314], as well as more general prioritising of qualities like reversibility [315], resilience [316] and flexibility [317].

Rather than resting hubristically on an ostensibly definitive picture in the balancing of benefits and harms, these precautionary strategies acknowledge stronger grounds for greater humility [276]. Instead of wishful thinking about the quality of risk information, they prioritise more humble measures to consider alternatives, explore uncertainties, maximise learning [246] and promote adaptability [318] in careful, reversible, step-by-step implementation [319]. Where there is uncertainty over probabilities, potential hazards do remain relevant in their own right – with particular care necessary where they might be irreversible [298]. And the dilemmas are accentuated where associated infrastructures might also prove to be especially inflexible [299]. All else being equal, where a range of innovation pathways

look as if they present similar balances of pros and cons, precaution simply highlights that it is reasonable to prioritise that which is more reversible over the less flexible alternatives [320].

At root, a key value of precaution lies in helping to free policy debates from the Panglossian fallacy that the most powerfully favoured innovation pathways are somehow necessarily the best or only option [321]. It reminds that particular values (other than profit), also need to be prioritised – especially around human health and environmental integrity [322]. This enables societies to discuss rationally and directly when it is right for governance deliberately to discourage or discontinue a particular entrenched trajectory [323]. The crucial point is, that precaution makes this possible without incurring existential anxieties over innovation in general. As a general principle, it offers a practical and flexible means to avoid simply relying on optimistic hopes that powerful vested interests will automatically be spontaneously relinquished or themselves become entirely benign.

And in this, precaution points to a further quality in research and innovation systems, namely diversity. Even though it is not a panacea, nor a 'free lunch' [324], nor self-evident in its composition, diversity is a vital consideration in research and innovation policy [77]. Like other strategies, it brings its own challenges and remains intrinsically a matter for political judgement. But in any given area, recognition of the importance of diversity encourages caution about concentrating resources in support of the particular innovations that happen to be favoured by the most powerful interests [325]. Diversity urges instead greater attention to alternatives, leading to more deliberately and systematically-constituted portfolios comprised of some balanced variety of disparate innovation pathways [77].

In these terms, diversity offers a remarkably practical way to help address several otherwise intractable innovation problems. It offers a 'resource pool' [326] helping to nurture creativity [68], mitigate lock-in [124], hedge against surprise [327], accommodate ambiguity [328], resolve irreconcilable interests [329], promote learning [246] and cultivate resilience [330]. And by fostering more intensive encounters between varying kinds of knowledge and practice, deliberate diversification can also help enhance innovation processes themselves [331] – and make them more effective and socially robust [332]. It is remarkable to find so many otherwise intractable challenges addressed (albeit always provisionally and incompletely) by a single operational strategy. And there exist plenty of useful tools to help focus more concretely at the level of diverse innovation portfolios, rather than individual programmes [333 334 335].

Consequently, deliberate diversification is one key pragmatic way to enable greater precaution, while also helping to diffuse unhelpful polarisation in debates over innovation [336]. This is aided by more explicit and measured pursuit of repertoires of innovations in particular areas, rather than single privileged supposedly 'sound scientific', 'evidence based', 'solutions'. Moreover, a focus on diversity may also help develop greater political tolerance, for the otherwise difficult – but inevitable – kinds of failure that are so essential to effective learning [337]. If commitments lie at the level of diverse portfolios rather than single supposedly 'no alternative' solutions, then it becomes easier to accept and justify the kinds of failures that contribute so much to learning.

To help realise these concrete benefits, however, diversity must move away from being a fig leaf or argument-of-last-resort for some otherwise ill-favoured but powerfully-backed choice [338]. It is all too easy to support otherwise indefensible proposals, simply on the grounds that "we must do everything" [339]. This invites powerful interests to insist on adoption of their own preferred policy, simply on grounds that every option must be pursued [340]. There are typically many kinds of diversity, each exclusive in some ways and inclusive in others [325 341]. So, as with individual innovation pathways, the detailed constituting of diversity also involves inherently political judgements. By urging this greater attention to diversity (as in other ways), precaution can be as much a spur to innovation in general, as a brake on any specific kind.

7. Three Key Conclusions

Formulating a adequate response to the challenges discussed in this paper requires being clear about the resulting practical implications for policy. Here, there have been many recent interventions developing concrete recommendations for research and innovation practices and the wider policy procedures and political debates in which these are set. The European Science Foundation reviewed key background in research and innovation systems across Europe [342]. The Expert Group on Science and Governance put this in the context of the European 'Knowledge Society' [295]. The Nuffield Council on Bioethics recommended new institutional ways more effectively to govern emerging technologies

[58]. The EPSRC identified a number of responsibilities to be encouraged across all actors in innovation systems [343]. An ESRC-funded 'new manifesto' explores some of the global implications [344]. And many other international initiatives contribute much further detail [345] [346,347]. But the general practical upshot is quite readily summarised in terms of three overarching principles: ***participation***, ***responsibility*** and ***precaution*** [305].

First, there is ***public participation in innovation***. Here, innovation strategies should more explicitly and transparently acknowledge the inherently partly political (rather than restrictively technical) nature of the interests and motivations driving contending pathways. This requires many forms of sincere, well-resourced, participatory deliberation – especially including the most marginalised interests [348]. This is not about fostering credibility, trust or acceptance, but about informing policy and helping substantively to determine the priority directions for research and innovation themselves [349]. Nor is participation about 'political correctness' or relativism about science (implying a position that 'anything goes' [350]). Indeed, it offers the most effective way to draw on wider knowledges in order to illuminate how dominant narrow understandings are often untenable. In essence, public participation in innovation is simply about more rigorous exploration of specific ways in which legitimate judgements about 'benefits', 'excellence', 'relevance', 'risk', 'evidence' and 'impact' all depend in part (but irreducibly), on contexts, values and assumptions.

In other words, public participation addresses the fact that what counts as a positive direction for research and innovation in any given area is inherently 'plural and conditional' [134]. 'Plural', because a number of contrasting pathways are typically equally valid [351]. 'Conditional', because this validity depends partly on perspectives and circumstances. A rich variety of carefully-developed inclusive, participatory and deliberative practices are available to address this challenge, with varying kinds of value in different circumstances [352] [353] [354] [355] [356] [357] [358] [359]. And crucially, participation does not just mean talking about innovation, but also inclusion in the means for supporting the actual doing of innovation itself [7] [84] [199] [345] [360] [361]. Here, there are key roles for the creative arts, humanities and local communities as well as workers and civil society more generally. Some approaches are more formally structured than others – involving 'uninvited' as well as 'invited' participation [362]. Together, these help 'open up' deeper and wider explorations of practical alternatives [314]. In this way, diverse styles of public participation supplement, enrich and inform (rather than substitute), the conventional procedures of representative democracy [363]. And freed from pressures to pretend at (potentially enormously expensive and protracted) ostensibly singular definitive 'evidence based' status, unfolding processes of innovation can become not only more democratically accountable and legitimate, but also more efficient and timely.

Alongside (and mutually reinforcing) greater participation, there is a second major policy imperative. This is for ***all actors involved in research and innovation processes*** – especially the most powerful – to assume more direct and explicit ***responsibility*** for the consequences and uncertainties of their activities. This in turn requires serious efforts on the part of innovators to be reflective in anticipating, analysing and addressing the impacts that might arise, as well as their attendant ambiguities and unknowns. It helps avoid the "organised irresponsibility" of otherwise 'passing the buck' to insurers, regulators, victims, the state, or 'society' at large to deal with inevitable unintended and indirect outcomes [364]. And (assisted by participation) responsibility involves being more openly accountable for motivating aims and interests. So, responsibility is not about aspiring – let alone claiming – to predict or control consequences [365]. Nor is it abut simple exhortations to trust [366]. Instead, responsibility is about trustworthiness [367]. It means going beyond conventional narrow institutional and economic interests, to care – and be accountable – for wider social and environmental concerns and implications.

A crucial aim of responsibility is that scientists, engineers, businesses, regulators – and government itself – move away from fixations merely with 'risk' around whatever are the particular privileged pathways for innovation in given fields. Instead, responsibility on the part of these influential actors, helps inform and open the necessary space for participation by others: by illuminating contending motives and a range of alternative directions for progress. Nor is there anything about this, that necessarily impedes decision making on innovation – or makes it more protracted or burdensome. Indeed, by helping to avert ill-advised trajectories at an early stage, participation and responsibility can assist innovation to become more effective in addressing diverse social values of a kind that might otherwise invite a costly backlash [62]. But there do arise here, particular responsibilities for the media. The discussion in this paper has shown that it is quite simply irresponsible to pretend (as is too often

the case [368]) that science and technology are free of interests, values or alternatives [369] [370]. What is required instead, is less simplistic and romantic portrayals of technical expertise [371]. The media hold especially important responsibilities for enabling more realistic, mature and open debates about the inherently contestible and power-laden nature of both scientific knowledge and technological innovation [372].

This leads to the third and final general policy implication. This is, that greater and more deliberate efforts are needed to moderate the powerful forces of closure and lock-in in science and technology. It is here that this paper has shown the particular value of ***precaution in regulation***. Rather than treating existing patterns of research and innovation as value-free, the precautionary principle strikes an explicitly stronger balance in favour of human health, environmental integrity and social well-being in the steering of priority directions. Thus guided (but not determined) by precaution, participation and responsibility can explore and elucidate more clearly what might be meant by these values in any given context. So together, these complementary principles and practices help provide a selection and balancing process, to harness incumbent and energetic private interests. In particular, precaution directly addresses the tendencies for uncertainties, ambiguities and ignorance to be closed down in the most convenient directions, as if they were just 'risk'.

When innovation is recognised as a branching rather than single-track process, it becomes clear that precaution is also not about impeding innovation, but steering it in ways that better favour human health and the environment. Acknowledging the scope for systematic deliberation over values, priorities and alternatives under uncertainty, precaution broadens out risk regulation to allow greater space for responsibility and participation – and greater consideration for a wider plurality of issues, options, perspectives and scenarios. This can help enable entrepreneurs, small business, new entrants, civil society groups and marginalised communities (as well as government) to better challenge established trajectories. As we have seen, precaution also implies a greater focus on qualities of diversity, flexibility and responsiveness in technology strategies. And a final key lesson of precaution is that regulation and innovation policy should seek to respect and embrace (rather than manage or curtail) public mobilisation and critical dissent. In essence, precaution expresses the fundamental principle that – in innovation just as in science itself – reasoned scepticism fosters greater quality.

In concluding this paper, then, we can return to a point made at the beginning. In any given area, innovation is not so much about a race to optimise a single pathway, as a collaborative process for exploring diverse alternatives. Current noisy anxieties over 'falling behind' in single-track 'zero sum' competitive innovation 'races' are misleading and counterproductive. They can conceal underlying motives, interests and alternatives – and supress the associated politics. Instead, inter-related practices of ***responsibility*** among researchers and innovators, ***precaution*** in regulatory processes and ***participation*** in policy making and innovation itself, can help innovation escape from these restrictive fear-driven technical imperatives. They illuminate instead how innovation is fundamentally about the politics of contending hopes [39]. Most importantly of all, it is in these ways that narrow technocratic ideas of a knowledge economy [295], can give way to the nurturing of a more inclusive, rational and vibrant ***innovation democracy***.

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Session 1 - Introduction
Presentation of the background studies

“From Bio to NBIC convergence – From Medical Practice to Daily Life”

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Abstract

The study “From bio to NBIC – From medical practice to daily life” highlights three technological trends which might be very relevant for the Committee on Bioethics. First of all, new types of developments are observed within the medical domain: from neuro-modulation techniques to molecular medicine. The study further shows that NBIC convergence enables the application of biomedical technologies outside the professional medical domain. Finally we see, as a result of this development, an increasing use of biomedical tools and bio-data for non-medical purposes, like gaming, entertainment, marketing, coaching, and human or social enhancement.

Please see the Bioethics Unit website:
https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=0900001680307575

Session 1 - Introduction
Presentation of the background studies

“Report on ethical issues raised by emerging sciences and technologies”

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Abstract

Research and innovation are particularly difficult to govern because they create novelty and surprise. The implementation of technology into society is a complex, open-ended and unpredictable process. The full extent of risks and side-effects can only be known by experience; and by that time they may be irreversible due to their magnitude or their entrenchment into societal infrastructures or human culture. Political and regulatory action accordingly has to include an element of anticipation, acting upon sociotechnical imaginaries, that is, narratives that imagine the future of science, technology and society and their interactions.

Sociotechnical imaginaries have real influence on research practice and policy, and they can be an object of governance. The production of sociotechnical imaginaries has been dominated by scientists, innovators and investors. Lately, however, many European governments, the USA as well as the European Union devote more effort into “soft governance” to democratize the processes of agenda-setting for research and innovation.

Sociotechnical imaginaries can also be taken as early (and uncertain) signals and early warnings. They may warrant monitoring schemes. They may also be taken as worst case scenarios that warrant regulation, such as with human cloning (prohibition) or xenotransplantation (comprehensive safety schemes).

In the report we discuss three sets of scientific and technological developments as paradigmatic cases, labelled as neuro, nano and ICT, respectively. In the full report, we also briefly discuss three

cross-cutting aspects: (1) the blurring of the line between the medical and the non-medical domain, (2) the ethical issue of global divides and equitable access and (3) the particular ethical challenges of military use of technologies.

Neuroscience as a Paradigmatic Case for Challenges to Human Identity and Integrity. In 1932, Aldous Huxley published his dystopian novel *Brave New World*. In a remarkable accomplishment of anticipation, Huxley imagined technologies of human enhancement, persuasive technologies and personality-altering technologies. Ethical considerations pertain not so much to essence or novelty as to magnitude, irreversibility, traceability and manipulation, as will be exemplified below.

Human Enhancement. The following technological capabilities are plausible scenarios: Directed and tailored modification of human genetic material in human individuals (germ line); pharmaceuticals and machines (prosthetic limbs and organs) that increase or improve physical, sensory and/or mental capabilities of humans; and devices that establish a functional brain-computer interface, with bidirectional communication.

Genetic modification of human germ line, that is, inheritable changes in human genetic composition, is generally seen as unacceptable and illegal. Still it is unwise not to discuss this possibility in order to take precautions or other measures.

Another important issue is that of fair competition in games, sports and work, including the access to the enhancement, and the right to abstain from or avoid the enhancement. Coercion, social pressure and direct command may threaten the right to abstain or avoid. It would need political action to protect the integrity of the individuals in work life against expectations which muster the ethical weight of the good of the larger number. There is good reason to consider measures to monitor technological developments and continuously evaluate the need for preventive or precautionary measures to protect the right to abstain or avoid in the presence of direct or indirect pressure or coercion.

Persuasive Technologies. We highlight unnoticeable persuasion, such as in Facebook's "emotion contagion study"; enforced persuasion; persuasion on the basis of privileged access to knowledge or other resources; and high-precision persuasion, such as anticipated by neuro-economics and neuro-behavioural sciences. As for the latter, full control of the human brain is unlikely to be achieved. Nevertheless, some precision is likely to be gained to the extent that it might dismantle the conditions for individual autonomy. Scientific ambitions of quantitative understanding, prediction and control of the human mind accordingly should be monitored for this risk.

Personality-Altering Technologies. Coarse personality-altering technologies and techniques have existed for some time. Examples include lobotomy, electroshock therapy, castration, psychoactive drugs, behavioural therapies and, to the extent that they can be called techniques, regimes of violence, containment and torture. Their stated intention have typically been to cure or alleviate mental illness and/or reform criminals, in particular "irrational criminals" such as sexual perpetrators and – in the rationale of authoritarian and totalitarian political regimes – political dissidents.

The emerging sciences and technologies will provide new tools for alteration of personality. The effects of psychoactive drugs are increasingly precise and sophisticated, as witnessed by the popularity of third generation anti-depressants (SSRIs). Their main effect appears to be a dampening of emotional states whereby the magnitude of strong negative and positive emotions is decreased.

In our view, hardly any development within the emerging sciences and technologies causes more ethical concern than that of technology with the potential for personality alteration. The existence of Deep Brain Stimulation (DBS) is a proof in principle of the possibility of dramatic non-disruptive personality-altering technologies. The 20th Century taught the world that authoritarian and totalitarian governments spare no effort in changing the belief structures, desires and personalities of their population. Personality-altering technologies are attractive from the point of view of non-democratic powers. The case made by Huxley in *Brave New World* is that totalitarian power and the pervasiveness of such technologies may reinforce each other synergistically.

It will not be easy to monitor and regulate research and innovation in this field. Prospects of medical applications may justify research. As with psychoactive drugs, however, a function creep may easily occur by which more and more applications are considered legitimate.

Nanotechnology as a Paradigmatic Case for Challenges of Uncertainty and Complexity. The ethical issues of the various parts of nanotechnology are rather different; those closer to the converging technologies are similar to the ethical issues of biotechnology and neuroscience. Still, there is one general ethical issue, namely that of strict uncertainty and complexity.

Under conditions of uncertainty and complexity, one cannot know in advance whether ordinary procedures of risk assessment and risk management will be able to detect and manage the harms and

hazards. Worse, there is no way of ensuring in advance that a real-life situation is not one of uncertainty, ignorance and complexity.
There are two reasons why uncertainty and complexity are particularly important with regard to nanotechnologies. First, there is scientific reason to expect surprising side-effects of nanostructures that cannot be predicted and controlled in advance. It remains to see the extent to which they can be detected early or if we will encounter new "late lessons" similar to asbestos, DDT and thalidomide. Secondly, the scientific belief in control is a leitmotif in the dominant sociotechnical imaginaries of nanotechnology. The nano scientific community actively creates and introduces uncertainty into the world but is by its own thought-style less prone to understand it. How can and should nanotechnology be governed? The Council of Europe may play a role in the development of political and institutional thinking in this regard, devising a framework for such institutions that could improve the safety of citizens, societies and the environment.

ICTs as a Paradigmatic Case for Challenges to Human Autonomy and Privacy. With regard to ICTs and the issues of privacy we highlight three observations, on the convergence of data gathering into so-called Big Data; on the data gathering and storing actors; and on the effect of Big Data on the human condition and the penetration of the life-world by surveillance technologies, respectively.
Convergence into Big Data. With the increasing interconnectedness and compatibility of devices for data acquisition, storage and transfer, comprehensive sets can be made of personal data, covering ever more aspects of personal life. There will be even larger amounts of biophysical/health information monitored by personal health devices, smart clothes and other instances of the Internet of Things. A lot more information can be obtained with a biological sample that can be analysed for DNA structure and protein levels. Furthermore, devices for remote surveillance are becoming more sophisticated. We recommend that more attention is given to the comprehensiveness of this reality, a reality that is more than just the sum of its parts and that is no longer adequately governed by laws and regulations that attend to each individual fields of application.
Who is Watching? In Orwell's novel *1984*, "Big Brother" is the personified embodiment of a totalitarian government. Recent public scandals indicate the development of a type of political regimes that in many respects are constitutive liberal democracies but still develop comprehensive policies of mass data collection upon their own citizens as well as abroad. Clearly, international governance initiatives are needed to come to terms with this situation.
Moreover, large private enterprises, such as Facebook and Google, have mass data collection as the central element of their business model, exactly because a comprehensive data set is of much higher information value than a simpler one. The respect for autonomy and the right to privacy are threatened by this type of business model, and we cannot see that citizens, civil societies or public authorities have been able so far to decelerate the expansiveness of their mass data collection practices. The magnitude of this challenge calls for coordinated international action.
The Panopticon, Governmentality and the Right to Private Life. What is at stake is the possibility of having an everyday life without being visible all the time. We are reminded of the *Panopticon*, which in Bentham's original idea was a design for a prison. In wealthy countries many surprising health problems emerge: eating disorders, pervasive dissatisfaction with own body appearance and a pathological lack of self-esteem and purpose. The *Panopticon* provided by ICTs is likely to aggravate this situation. It has been argued that the possibility to perform everyday undertakings without being seen, monitored or noticed, may be fundamental to the development of a sane personality. Current developments of convergence into comprehensive Big Data performed by powerful public and corporate actors as well as by the public itself, are a large-scale social experiment in which the right to privacy as a basic element in the human conditions for personality development is at stake.

Implications for the Protection of Human Dignity and Identity, the Right to Integrity, and Other Human Rights and Fundamental Freedoms. *(a) Convention on Human Rights and Biomedicine.* The scope of the Oviedo Convention is the application of biology and medicine. Today, almost 20 years after the convention was made, also other sciences and technologies pose ethical challenges to human rights and dignity of the human being. We observe that several of the rights protected by the Oviedo Convention are at stake in the emerging sciences and technologies:
Article 1: Dignity, identity and integrity of all human beings. Identity is threatened individually and collectively by persuasive and personality-altering technologies, and collectively by enhancement technologies that could lead to human speciation events. Identity is also under threat if comprehensive surveillance if conditions for personality development are hampered by the undermining of the possibility of having a private life and exercising the right to privacy. *Integrity* may be threatened by direct and indirect pressure and coercion to subject oneself to enhancement technologies, whereas

mental integrity is at stake as collateral effects of personality-altering technologies. *Dignity* is always difficult to define; however, we believe that all of the examples in this paragraph also constitute a threat to human dignity. In particular, enforced or unnoticeable persuasion or personality alteration violates human dignity.

Article 2: Primacy of the human being. This principle is clearly at stake today when governmental and corporate interests perform research and innovation to develop new technological opportunities for mass data collection and persuasion. It is also at stake in experimental research on human subjects for which there is inevitable uncertainty about collateral effects, in particular when performing interventions on the human brain, which is known to be a richly coupled neural network and a priori can be expected to experience side effects.

Article 3: Equitable access to health care. This principle is at stake in global divides such as the digital divide and the nano-divide insofar as technological developments create or change infrastructures that exclude those who do not possess access or knowledge to use the technology.

Article 10: Private life. In the Oviedo Convention this principle is invoked with respect to health information. What can be learnt from the emergence of mass data collection, Big Data and the blurring of the line between the medical and the non-medical, is that more than just health information as conventionally understood can be critical for the possibility to exercise and uphold a private life. Indeed, already a payment card or a smart power meter, if unregulated, can undermine this right.

(b) Convention for the Protection of Human Rights and Fundamental Freedoms. Below we briefly comment on the relevance of certain articles that present a larger range or scope of human rights and freedoms than immediately visible in the Oviedo Convention.

Article 3. Prohibition of torture. The wording of this article is "… to torture or to inhuman or degrading treatment or punishment." Persuasive and personality-altering technologies, also already existing ones, provide new possibilities for inhuman or degrading treatment. One can only imagine what deep brain stimulation as a correctional measure or punishment could entail.

Article 8: Right to respect for private and family life. We observe that this right is not limited to the scope of biology and medicine but applies generally. Specifically, there may be an exception for the necessity of the economic well-being of the country, which is no carte blanche to mass data collection as a business model for multinational corporate interests.

Finally, we will mention *Article 9: Freedom of thought, conscience and religion.* Often, the article is invoked when the right to manifestations of these freedoms is violated. However, as we have explained above, the right to freedom of thought and conscience itself, that is, freedom from interference and intervention on cognition and brain processes, is indeed at stake in the development of persuasive and personality-altering technologies.

Recommendations

(1) The developments within emerging sciences and technologies pose serious ethical issues and concerns. The Council of Europe has an important role also in being a forum for continuous reflection and discussion needed to root the answers to the new ethical issues in shared European values and shared criteria for action. The scope of the bioethical work of the CoE should be permanently expanded to cover the developments in nano-, neuro-, info- and cogno- science and technology.

(2) In line with the European heritage of democracy, a significant task for bioethical work is to play a proactive part in the democratization of the production of sociotechnical imaginaries and thereby our common scientific and technological future, for instance by developing and encouraging participatory foresight exercises, upstream engagement and other practices of what has been called "responsible research and innovation" (RRI).

(3) Several technological fields call for continuous monitoring with respect to the ethical issues they pose. This includes human enhancement, persuasive and personality-altering technologies and other technologies that interfere with the preconditions for enjoying fundamental rights and freedoms. CoE is encouraged to take a proactive role in the development and harmonization of such ethical monitoring schemes and practices.

(4) In our report, we have observed threats to several fundamental rights and freedoms laid down by the Oviedo Convention as well as the Convention for the Protection of Human Rights and Fundamental Freedoms. A number of possible ways forward can be imagined, including new Recommendations on specific technological fields and even the expansion of the scope of the Oviedo Convention to the formulation of a new convention for ethics of science and technology that falls outside the medical realm. We have indicated the main fundamental rights and freedoms that we believe to be at stake.

(5) Another way forward is to discuss how measures can be taken when the normative basis and the legal instruments are present, but new practices in the world of science and technology are seen to

systematically violate them. For instance, the report has raised the question if not the new phenomenon of mass data collection and surveillance as a business model indeed is a violation of fundamental rights and freedoms of citizens.

Please see the Bioethics Unit website:
https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=090000168030751d

Session 2 – Technology, intervention and control of individuals Introductory presentation: what is at stake?

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Abstract

The fate of the human subject in the age of intimate technologies and Big Data

A new chapter in the history of technology seems to be unleashed. Until recently, man-made technologies basically functioned as prostheses, as external prosthetic *extensions* of human bodies, directed towards the outside world, allowing us to interact with and manipulate objects more effectively, eventually transforming humans into 'prosthesis-gods' (Freud 1930). Currently, technological devices have begun to move *inwards*: *entering* our bodies and brains, functioning as *implants* rather than as extensions. Self-monitoring is an important objective of this trend. Due to recent developments in technosciences, such as synthetic biology, tissue engineering and nanomedicine, our sway over the human 'condition' (in its literal, biomedical sense) is increasing, down to the molecular level, and up to the point of becoming uncanny. New options for drug delivery and bio-implants are entering (pervading) human bodies and brains. On the one hand, this may be seen as strengthening human autonomy and agency. On the other hand, we must consider the possibility that we are the targets rather than the agents of this process. Rather than being in control, we may become increasingly dependent on these new technologies, emerging in the boundary zone between therapy and enhancement. On the one hand, intimate technologies allegedly open up new practices of the Self, enabling individuals to become the 'managers' of their own life and health. On the other hand, human beings are controlled by the gaze of the Other, which invokes a sense of unease. An exemplification is the Snyderome project. A prominent geneticist was closely monitored over the course of 14 months, measuring everything, resulting in the integrative Personal Omics Profile, a comprehensive omics portrait ("extremely high coverage"), combining "deep sequencing" with more than 3 billion measurements of molecules. This portrait is highly personal, but at the same time highly impersonal: opening up individuals to a digital panopticon: a molecularised version of the 'voice of conscience' in the form of a computer monitor, informing us that we must change their life on a daily basis: the superego of intimate technologies in the terabyte age. What is the fate of the human subject in the era of Big Data and intimate technologies?

'Extimate' Technologies: Empowerment, Intrusiveness, Surveillance

Introduction

In the opening scene of the futuristic cult novel *Accelerando* by Charles Stross (2005), ICT wizard Manfred (the novel's key protagonist) arrives in the plaza in front of Amsterdam Central Station with eyeballs "powered up" (p. 3) and equipped with special high-tech glasses which keep him acutely up-to-date, so that he lives minutes (or even days and weeks) into other people's future, assimilating gigabytes of content every day, just to stay current (p. 5). Soon, he encounters some other early adopters of smart technologies, like-minded youngsters, spreading "clouds of electronic emissions" as they move about. *Accelerando* reads like a literary laboratory, inviting us to explore the emerging future, with Manfred as our guide, or research subject. How will human existence and the human life-world be affected (perhaps we should say: infected) by this upcoming avalanche of high-tech and miniature devices, also known as intimate technologies?

The book *Radical Evolution: the Promise and Peril of Enhancing our Minds, our Bodies – and what it means to be Human* by science author Joel Garreau (2005) has a similar objective: exploring the emerging future, albeit this time by visiting and interviewing pioneer researchers in their laboratories. The general message is that we are reshaping ourselves, equipping ourselves with embedded devices, for x-ray vision of infrared vision (via retinal implants) for instance, or with exoskeletons. We are approaching an inflection point in history, Garreau argues. For millennia, technologies tended to be aimed outward, allowing us to control and reshape our environment: the objects we encountered. Now, however, the direction seems to be suddenly reversed, as technologies are taking an inward turn. We ourselves (our human bodies and brains) are now increasingly becoming the target of choice. New technologies have begun to merge with our minds, our memories, our metabolisms, our moods, our personalities even: we are really entering the era of "engineered evolution" (Garreau 2005, p. 6). A plethora of (more or less plausible, more or less futuristic) examples is exhibited and assessed in Garreau's fascinating panorama. Besides inserting various kinds of retinal and cochlear implants, or bioinspired materials and tissues produced from stem cells into our bodies we could, for example, add a new artificial chromosome to the nucleus of our cells, thereby providing additional plug-in-points as it were, where genetic modules could be implanted with additional features. This auxiliary chromosome would be a universal delivery vehicle for bio-molecular implants, including an on-off switch activated by injections (p. 117).

Similar prospects are invoked by the recent report published by the Dutch Rathenau Institute entitled *Intimate Technologies* (van Est et al, 2014). Electronic gadgets are shrinking in size, coming closer, becoming wearable, the authors argue, they are now just on the outside, on our skin, while cochlear implants, deep brain stimulation electrodes etc. have already entered our bodies. And indeed, the advent of intimate technologies is being heralded by a chorus of authors. The relations between technologies and human bodies are becoming increasingly intimate, Lucie Dalibert (2014) claims. Contemporary objects such as wearable computers are presented as intimate machines; we become increasingly dependent on them and they demand that we focus daily attention on our increasingly intimate relationships with them (Turkle 2004). New technologies are pervading our lifeworld, they are becoming *us*. Micro-implants, health monitoring technologies and Google Glass exemplify new types of gadgets that are increasingly getting closer to, or even penetrating under our skin, giving rise to an intimate interplay between bodies and technologies (Lettow 2011).

In *Polar Inertia*, Paul Virilio (2000) has argued that three technological revolutions can be distinguished. The first revolution began in the 19th century and notably involved transport (trains, cars, airplanes, etc.). The second revolution emerged in the 20th century and focussed on technologies of transmission (radio, TV, etc. up to the computer and the Internet). The third (currently ongoing) revolution entails processes of 'miniaturization' and is about to culminate in the colonisation of the intimacy of the human body with the help of nanotech implants. This is the challenge currently facing us, as Virilio sees it: how to cope with technologies that are actually inhabiting us?

Ernst Kapp (1877), founding father of philosophy of technology as a research field, argued that traditional instruments were actually projections or exteriorisations of bodily organs, allowing us to control and manipulate objects in the outside world (Lemmens 2008). A hammer, for instance, can basically be regarded as an extension of (and as a robust version of) a human fist. The direction of movement was from the inside (the sphere of desire) towards the outside (the recalcitrant

environment). Technology is basically the mechanisation of the organic, eventually transforming human beings into "prosthesis-gods" (Freud 1930/1948). But we are currently experiencing a dramatic reversal. As indicated, miniature gadgets are now moving from the outside towards the inside, they are now turned towards ourselves and entering our bodies and brains. The micro-mechanic is implanted in the organic and may gradually come to replace our most intimate organs and tissues. We ourselves have now become the target of change, allegedly resulting in an increased modifiability (and reduced recalcitrance) of the human body. In the next session, I will assess these claims, concerns and developments from a (psychoanalytically inspired) philosophical perspective.

Extimate technologies: a psychoanalytic assessment

As indicated, I will use a psychoanalytic framework of interpretation to assess the emerging technologies of today, as part of a diagnostics of the present. What is it that makes these smart, embedded gadgets so alluring and disconcerting? What is at stake? To articulate the ambivalence these technologies evoke, a concept coined by Sigmund Freud (1919/1947) may be helpful, namely the concept of the "uncanny", referring to that which is both familiar and unfamiliar, that which positions itself in the boundary zone between natural and artificial, the living and non-living. But the uncanny also refers to that which should have remained hidden, but is now being opened-up and exposed. The uncanny positions itself in the intermediate spaces between bodies, automatons and corpses and seems especially apt to capture anxieties raised by biotechnical artefacts (Assoun 1997). The optimal exemplification of the uncanny is a body part, a 'partial object', an organic component which has become detached from the body as a whole: a hand, an eye, a breast or a foot, something that has become disconnected, or has been replaced.

Uncanny entities such as glass eyes and plastic hands have been around for while however, so the question is: what is so new about intimate technologies: where can the discontinuity be located? The most pertinent difference between traditional prostheses and intimate gadgets seems to reside in the size of the latter, in combination with their embeddedness. They really seem to become part of the daily life of the body as a whole. They fil up invisible gaps, but instead of really solving our deficiencies, they may easily become objects of daily concern in their own right. Indeed, they are likely to become quite demanding. They monitor us and continuously *look* at us.

Building on Freud, the French psychoanalyst Jacques Lacan has coined a term that seems to capture the newness of these new technologies quite convincingly, namely the concept of the extimate: that which is both intimate and external (Lacan 2006; Zwart 2014). Instead of 'intimate technologies', therefore, I would rather speak of 'extimate technologies' because, on closer inspection, these gadgets are not really intimate at all, and their status is much more ambiguous. Lacan's concept of the extimate refers to that which is both intimate and foreign, both embedded and intrusive, both alien and familiar, both life-saving and disrupting. The extimate is that which offers us a life-line, while at the same time opening up daily existence to the gaze of the Big Other, the electronic super-ego, persistently trailing us and spurring us to change our lifestyle, our way of living, giving rise to permanent (self)-monitoring and intense surveillance. Let me elucidate this concept with the help of an example.

The Snyderome case

In 2012, Michael Snyder and his research team (at the Department of Genetics, Stanford University) published the 'integrative Personal Omics Profile' (iPOP) of a single individual, a 54-year old male volunteer, whom they had closely monitored over the course of 14 months (Chen et al 2014).[5] This longitudinal case study resulted in a comprehensive 'omics' portrait ("extremely high coverage"), combining "deep sequencing" (of the genotype) with more than 3 billion measurements of molecules (i.e. the person's phenotype). Although the research subject was a "healthy individual", the project at the same time amounted to a case study in the sense of a *Krankengeschichte* as two minor viral infections, together with (unexpected) evidence of the subject's propensity for diabetes, constituted the dramatic highlights of the story.

Soon, it turned out that the "male volunteer" of this N=1 experiment (surrounded by qualified personnel and costly equipment) was none other than Michael Snyder himself, the department chair now acting

[5] The article listed forty-one authors with Michael Snyder acting as final and corresponding author.

as his own research subject of choice, turning his body into an omics laboratory. The experiment resulted in what has been referred to as the Snyderome[6] or even the Narciss-ome.[7] Snyder himself made it known that he plans to remain a study subject for life,[8] adding new sources of information as the process unfolds, including data procured from body samples such as breath, urine, faeces ('stool microbiome'), saliva, etc., in other words bodily materials released via various bodily apertures that are usually referred to in psychoanalysis as 'erogenous zones'.

Snyder's idea is that, via high resolution self-monitoring, human individuals will become the proactive managers of their own health. It will allow 'us' to take medicine into our own hands, with doctors merely acting as advisors. Individuals are expected to heavily wire themselves, so as to register pulse, heartbeat, stress (transpiration) and numerous other indicators continuously. The idea is that measurements of thousands of factors can be integrated through devices such as iPhones and compared with big data references, available 24/7 at open-source repositories (vast science clouds), after which the outcomes can be translated into every-day options (diet, exercise, etc.). It is expected that especially the aetiology of mystery symptoms (such as unexplained fatigue or depression) can thus be elucidated.

But rather than putting individuals in charge of their own health, the repositories which are set up to provide reference data (i.e. standards for normality) can easily become an electronic, molecularised version of the super-ego, the 'voice of conscience' of the terabyte age, the Big (digital) (Br)Other. On a daily basis, computer 'monitors' will be telling future individuals that they must change their lives in order to optimise somatic functioning, so that they can live up to normalcy standards, and postpone / mitigate the impacts of unhealthy life-styles and ageing. In other words, it would be a simplification to interpret the advent of extimate self-monitoring technologies merely in terms of 'empowerment'. I will conclude my analysis with a second case study, an anecdote taken from everyday experience.

Extimate technologies: a case study

Some weeks after attending the Strasbourg conference, I joined the daily cue on Saint Peter's square in Rome (where I participated in another scholarly conference, this time on neuro-enhancement) to visit the imposing Basilica. Many languages are spoken by visitors in this cue, coming from around the globe, while emails are checked and calls are made: a multilingual crowd. Finally, after half an hour of patience, it was my turn to pass the electronic surveillance gate: 21st century technology, positioned between two imposing marble pillars. I deposited all the electronic gadgets I was carrying with me (memory stick, iPhone, credit cards) on a small table before sliding through the clearance gate. Nothing happened, and a Swiss guard kindly waved, inviting me to enter. Right behind me, however, the electronic alarm system suddenly sounded, as an elderly Flemish couple wanted to pass the gate as well, but the woman quickly explained the situation by saying, in English, "My husband has two hips".

I was struck by her impromptu remark. It caught my ear for various reasons. First of all, it is an example of what Freud would call 'condensation'. Something is bypassed, replaced, concealed or camouflaged. What the woman actually intended to say was something like "my husband has two artificial metallic hip implants, and this is what the surveillance system is detecting", but uttering such a long and complicated sentence would have focussed attention on her husband's condition (already emphasised by the sounding system, so that he already had become the focus of attention of various impatient bystanders) even more. Something intimate, something which should have remained hidden, was unwittingly brought to the surface, accentuated even. As if the surveillance system was shouting into our ears: "Look people, this person has both his hips replaced!" Electronic surveillance gates are multiplying. We find them at the entrances, not only of museums and cathedrals, but also of airport gates, shopping malls, governmental buildings and in countless other places. Perhaps the woman and her ageing husband were tired of being reminded all the time of the presence of the latter's implants by electronic detectors. Perhaps it was a painful reminder of physical deficits which (Freudians would no doubt add) can easily be associated, consciously or unconsciously, with other physical problems centring on the pelvic zone, related to ageing.

[6] http://snyderome.stanford.edu/
[7] http://www.nature.com/news/the-rise-of-the-narciss-ome-1.10240
[8] https://www.genomeweb.com/sequencing/snyderome-study-suggests-much-gain-individuals-genome-molecular-profiles

Be this as it may, it must be an uncomfortable experience indeed to become the target of high-tech surveillance on a daily basis, as a side-effect of a medical treatment: i.e. the replacement of damaged bone tissue and cartilage by embedded prostheses. Therefore, the woman used a diplomatic, euphemistic term, in the hope that the surveillance officers would immediately understand what was meant, because artificial hips, once highly exceptional, have become quite common, although strictly speaking the sentence is a funny one, given the fact that everybody 'has two hips', - it is a basic ingredient of human anatomy. For Freud, condensation is a mechanism of defence, employed to conceal something that is considered embarrassing, threatening, painful or uncanny. Indeed, something which should have remained hidden is suddenly detected, emphasised even, namely the presence of an artificial and metallic 'something' hidden in what seems to be (based on outward appearance) a normal organic living body. These intimate, or rather 'extimate', metallic items, moreover, are detected and highlighted with the help of another instance of extimate technology: an electronic surveillance system which is able to screen us, to search and examine us, and which even seems able to enter our bodies, with the help of hyper-tech sense organs.

According to Jacques Lacan (1966), condensation basically works as a metaphor: a particular term is replaced by another, for instance when someone says "I see three sails on the ocean", where the word "sails" is actually used as a stand-in for "boats". Something similar occurs in the example given above, where the word "hips" is used as a stand-in for "metallic implants". A problematic signifier ("implants") is substituted by a less distressing, funny term ("hips"), poetic even, in an every-day sense, meant to take away the tension, because it would be uncomfortable, or even rude, to draw too much attention to the fact that this elderly person, surrounded by an impatient, cuing crowd, is actually a kind of cyborg. But the surveillance system is inexorable and automatically reveals what surgery, clothing and physiotherapy, in combination with the woman's condensed and jocular sentence, tried to cover up, namely the uncanny idea that this person has entered the world of cyborg-embodiment, via the presence of two implants in his pelvis.

The anecdote highlights the ambiguous, ubiquitous presence and function of extimate technologies in the human life-world in various ways. On the one hand, we could focus on the metallic hip implants themselves: embedded and hidden, as a piece of technology that has really entered the body. They have improved the husband's quality of life no doubt, but are bound to remain items of concern nonetheless. Will they continue to function properly, will they be electronically detected? On the other hand, we could focus on the electronic surveillance device as such, as a piece of technology that has entered the everyday world and is becoming ubiquitous, notably in public spaces. Indeed, these devices are multiplying, their presence is becoming pervasive. The implants will continue to evolve no doubt, so that one day, metallic versions will be replaced by biocompatible, quasi-organic biomaterials, intimately embedded within the body, but electronic surveillance devices will evolve as well, their precision and resolution will increase as well, so that the interaction between these two types of devices (electronic surveillance versus implants) will intensify. These electronic devices increasingly function as a kind of super-ego, reminding us of our deficiencies (and their built-in technological compensations), notably those we perhaps would like to forget or conceal (Zwart 2015; Hilvoorde & Landeweerd 2010).

Something similar would have happened if I would have forgotten to take out my iPhone, for instance, having grown so accustomed to its presence that I sometimes am no longer aware of its being-there, until the electronic beep of the surveillance system reminds me of the fact that I am becoming increasingly dependent upon this gadget, from which I am only temporarily disconnected, for a few seconds only. It is an enabling device, providing me with maps and apps and e-mails, but at the same time it is an intrusive gadget, allow the electronic panoptic Big Brother (or 'Big Other', as Lacan would phrase it) to trace me, to keep track of my whereabouts and doings, with the help of the "clouds of electronic emissions" produced by such an innocent-looking, extimate device. In other words, extimate devices enable various practices of the Self, no doubt, but compensation is due: I must allow the electronic Big Other to enter my private sphere and I must feed this Other continuously with personalised data in return.

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Session 2 – Technology, intervention and control of individuals Ethical and societal perspectives

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Abstract

I will study the ethical and societal problems arising from the emergence of new technologies in the field of doping and anti-doping controls.

Doping and technologies: ethical and societal perspectives

INTRODUCTION

The aim of this paper is to question the validity of the current policy of the World Anti-Doping Agency (WADA) and the international sports authorities. The relative inefficacy of anti-doping controls gives rise to serious ethical issues and problems for the sports judicial system. A very large number of athletes who take doping agents manage to slip through the anti-doping net. Consequently, the two main objectives of WADA policy – to ensure that athletes compete on a level playing field and to eliminate doping – have not been achieved.[9] The problem is a structural one. The anti-doping policy introduced by WADA since 1999 can be regarded as a large-scale social experiment. After almost 15 years of experimentation, it is time to take stock of this experiment to see whether the current banning policy is the best approach to minimise the harmful effects of doping. Recent cases have shown that in certain sporting disciplines, such as cycling, doping is endemic. The investigations carried out by the USADA into Lance Armstrong's US Postal Service team showed that in the early 2000s, the majority of cyclists taking part in the Tour de France were taking prohibited substances.[10] As far as we are concerned, therefore, we need to look at the issue of doping in sport from a pragmatic point of view, focusing on consequentialist ethics. From an ethical point of view, there are two key factors: minimising the risk to athletes' health and ensuring fairness in sport. From the point of view of health risks, it is far from certain that WADA's current policy is the best possible one inasmuch as, de facto, it

[9] The World Anti-Doping Code (Page 11) states that "The purposes of the World Anti-Doping Code and the World Anti-Doping Programme which supports it are to protect the Athletes' fundamental right to participate in doping-free sport and thus promote health, fairness and equality for Athletes worldwide" (World Anti-Doping Code, www.wada-ama.org).

[10] See the appendices of the Statement from USADA regarding the U.S. Postal Service Pro Cycling Team Doping Conspiracy: http://cyclinginvestigation.usada.org/.

has allowed large-scale underground doping to develop. From the point of view of fairness in sport, the current policy is far from satisfactory, insofar as its inefficacy puts those athletes who do not take doping agents at a disadvantage in relation to those who do so secretly. This leads to the highly immoral situation in which the winner is often the "best cheat", i.e. the shrewdest, the cleverest or the luckiest. Furthermore, regardless of health and fairness issues, WADA's prohibitionist policy produces a number of very worrying adverse effects. The doping issue should therefore be able to be discussed without any taboos or preconceived ideas. For this to happen, the various stakeholders (especially the athletes) must be allowed to express themselves freely. It is a complex question for which there is no simple solution. We need to have a wide-ranging, impartial public debate on the consequences of the doping policy, the legitimacy of resorting to performance-enhancing technologies in sport and on the kind of sports policy to be advocated to enable athletes to exercise their profession in the best possible conditions.

1. A new direction in the debate on performance enhancement in sport

Clearly, the debate on performance enhancement in sport is a very old one, but it has evolved considerably in recent years. There are, it would appear, two reasons for this: the creation of the World Anti-Doping Agency and the emergence of enhancement medicine.

— The creation of the World Anti-Doping Agency (WADA)

The renewed vigour in the fight against doping following the Festina affair in the 1998 Tour de France 1998 led to the creation of the World Anti-Doping Agency (WADA) and the application of a prohibitionist philosophy officially endorsed by the sports authorities. The aim of the World Anti-Doping Agency is to promote, co-ordinate and supervise the fight against doping in sport in all its forms. It was founded in 1999 as an independent international organisation. Its creation put an end to the relatively relaxed attitude to the fight against doping in the last decades of the 20th century. This political will to eradicate doping led to numerous athletes being suspended from competitive sport for periods of varying length and, indirectly, the imprisonment of renowned athletes such as Marion Jones. Some doctors and philosophers today believe that the aim of eradicating doping in sport is an unattainable ideal. Taking the view that WADA's policy is counterproductive, they advocate different pragmatic approaches, authorising doping under medical supervision.

In this paper, readers may have the impression that I am targeting the World Anti-Doping Agency and the way it organises the fight against doping. It just happens to be that WADA is the body with the highest profile and the one that receives the most media coverage. However, basically WADA has merely implemented an approach earlier developed by the Council of Europe, which was crystallised in the Anti-Doping Convention. The Unesco Convention draws very heavily on the Council of Europe Convention.[11]

I must therefore emphasise the similarity between the approaches underlying each of these three institutions (WADA, Council of Europe, Unesco). Via WADA, it is also the anti-doping philosophy of the Council of Europe and Unesco that is the focus of my criticism.

— The emergence of enhancement medicine

The second reason conferring on the issue of performance enhancement in sport a philosophical and ethical dimension which it did not previously have is the inclusion of the doping issue in a much broader field – enhancement medicine. The blurring of the boundaries between conventional therapeutic medicine and enhancement medicine is one of the main characteristics of 21st century biomedicine. In contemporary biomedicine, the new drugs and therapeutic technologies can be used not only to treat patients but also to improve certain human capacities. A recent survey showed that taking cognitive enhancement medicines to improve academic performance had become common practice in American universities.[12] The substances used by athletes to enhance their performance, such as amphetamines, erythropoietin, corticosteroids and growth hormone were first used for therapeutic purposes. Similarly, medical technologies such as gene therapy and stem cell

[11] See the text of the Council of Europe's Anti-Doping Convention (http://www.conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?CL=ENG&CM=8&NT=135&DF=04/04/2013) and the Unesco International Convention against Doping in Sport (http://portal.unesco.org/en/ev.php-URL_ID=31037&URL_DO=DO_TOPIC&URL_SECTION=201.html).

[12] B. Maher, Poll results: look who's doping, *Nature*, Vol. 452, 2008, p. 674-675.

injection are likely to be used by athletes to enhance their performance. This represents a paradigm shift in medical practice. Another branch of medicine has imperceptibly developed within conventional therapeutic medicine, with the aim not of curing but of enhancing – "doping medicine". In his book *Better than Well*, the philosopher and bioethicist Carl Elliott analyses the multiple aspects of enhancement technologies in contemporary American society.[13] Over the last ten or so years, first of all in the United States and then in Europe, many authors – doctors, philosophers, bioethicists, legal writers – have addressed the issue of enhancement technologies.[14] Medicine is no longer solely therapeutic. Some quarters expect it to be used for performance enhancement and "perfecting" human beings, including in the field of sports. In this context, competitive sport could become one of the main laboratories of "enhancement".[15] Athletes are often prepared to take risks, including the use of doping agents or experimental technologies in order to enhance their performance. In order to win competitions, beat records or win medals, certain athletes are willing to take part in a large-scale experimentation carried out thus far in secret. The conjunction of sport and enhancement biotechnology raises questions of ethics, philosophy and the sports justice approach for which there are no simple answers. The policy of banning and punishing doping is surely not the only possible strategy. There are ethical (and political) positions other than the approach underlying the action taken by WADA. We will have to wait for confirmation of the inefficacy and probable failure of the current anti-doping policy before other solutions are trialled on the ground. Today, some people, supporters of a liberal ethic, are already calling for the legalisation of enhancement technologies, under supervision, in sport. Their arguments should be taken seriously, even though legalisation itself also has a number of undesirable consequences.

2. Biotechnology, enhancement and sport: the example of gene therapy

"What is clear ... is just how impatient some coaches and athletes are to find new and ingenious ways to cheat. First it was steroids, then EPO [erythropoietin], then human growth hormone – and now the illicit grail seems to be gene therapy"

(T. Friedmann, O. Rabin, T. S. Frankel, "Gene doping and sport", *Science*, 327, 2010, p. 647-648).

"Helping athletes was the last thing on my mind. But every time a new genetic study about boosting muscle quality or blood supply or bone strength is published, the calls start up again. These people cruise the internet for anything they think could give them a chance to become stronger, faster athletes"

(H. Lee Sweeney, quoted *in* Robin McKie, "The drugs do work", *The Observer Sport Monthly*, 4, February 2007).

In the 20th century, doping in sport evolved in line with advances in pharmacology (amphetamines, steroids, growth hormone, erythropoietin, etc.). For some years now, developments in gene therapy have provided new means of enhancing performance in sport. The blurring of the boundaries between therapeutic medicine and enhancement medicine is perfectly illustrated by the example of the potential uses of gene therapy in sport.[16] Gene therapy offers techniques for the

[13] C. Elliott, *Better than well: American medicine meets the American dream*, New York, W.W. Norton, 2003.

[14] For a historical, philosophical and ethical approach to enhancement technologies, the following works may be consulted: J.-N. Missa, and L. Perbal, *"Enhancement". Éthique et philosophie de la médecine d'amélioration*, Paris, Vrin, 2009; Julian Savulescu and Nick Bostrom (ed.), *Human Enhancement*, Oxford University Press, 2009; J. Harris, *Enhancing Evolution. The Ethical Case for Making People Better*, Princeton University Press, 2007; J. Goffette, *Naissance de l'anthropotechnie. De la médecine au modelage de l'humain*, Paris, Vrin, 2006; J. Hughes, *Citizen Cyborg: Why Democratic Societies Must Respond to The Redesigned Human of the Future*, Cambridge (MA), Westview Press, 2004; D. Lecourt, *Humain, posthumain*, Paris, PUF, 2003; S. Rothman, D. Rothman, *The Pursuit of Perfection: The Promise and Perils of Medical Enhancement*, New York, Pantheon Books, 2003; J. Habermas, *The Future of Human Nature*, Cambridge, Polity Press, 2003; The President's Council on Bioethics, *Beyond therapy: Biotechnology and the Pursuit of Happiness*, New York, Dana Press, 2003; F. Fukuyama, *Our Posthuman Future: Consequences of the Biotechnology Revolution*, Farrar, Straus and Giroux, 2002; J. Glover, *What Sort of People Should There Be?*, London, Pelican, 1984.

[15] On this subject see the book by Isabelle Queval, *S'accomplir ou se dépasser. Essai sur le sport contemporain*, Paris, Gallimard, 2004.

[16] Chapter 3 – entitled "Superior performance" – of the report *Beyond Therapy* by the President's Council of Bioethics takes a detailed look at this question. See The President's Council on Bioethics, *Beyond Therapy: Biotechnology and The Pursuit of Happiness*, New York, Dana Press, 2003 (www.bioethics.gov). See also the transcript of the hearing of H. Lee Sweeney by the

genetic modification of physiological functions relating to athletic performance. Genetic recombination technologies could not only alleviate the symptoms of diseases, such as muscular dystrophy, but also enhance muscle stamina in older persons or improve athletes' performance. Dozens of genes affecting sport performance have been identified which could be modified by genetic recombination. Scientists have created transgenic mice which have exceptional "athletic abilities".[17]

One of the first experiments in genetic recombination which could have sports performance-enhancing consequences was carried out by Se-Jin Lee, a professor in molecular biology at the Johns Hopkins Medical School in Baltimore. Lee identified the function of myostatin, a protein which inhibits muscle growth.[18] Experimenting on mice, Lee deactivated the animals' gene encoding synthesised myostatin. He obtained hypertrophic mice. When he published his results, Se-Jin Lee received e-mails from not only patients suffering from muscular diseases, but also athletes and body-builders wishing to increase their muscle strength artificially, and keen to experiment with gene therapy on their own bodies. In 1998, H. Lee Sweeney, professor of physiology at the University of Pennsylvania, published the results of an experiment on mice genetically recombined to produce IGF-1 *(insulin-like growth factor)*, a substance that promotes muscle anabolism. The American press dubbed Sweeney's hypertrophic mice "Schwarzenegger mice". He too received numerous requests from athletes wishing to benefit as soon as possible from scientific advances.[19] He claims that he was even contacted by the coach of an American football team and the coach of a wrestling team, both ready to subject their teams to genetic experiments. "No matter what I say to them about it being dangerous, it doesn't slow them down," says Sweeney.[20] The possibility of gene doping has also been further raised by the work of a team led by Richard Hanson. The mice genetically modified by Hanson have outstanding athletic qualities.

The performance of those mice was improved spectacularly. On a treadmill, they could run up to six kilometres at a speed of 20 metres a minute, whereas normal mice stop after 200 metres. These changes are linked to the overexpression in the skeletal muscle of a gene, the enzyme "cytostolic phosphoenolpyruvate carboxykinase" (PEPCK-C). This enzyme governs the process for synthesising glucose, the "fuel" that cells need, and glycerol, found in fats. The mice's improved running capacity is explained by their 40% higher consumption of oxygen and their low production of lactic acid. Interviewed by the UK daily, The Independent, Richard Hanson accepted that it might be possible to use the findings of his research to develop new drugs that could improve muscle performance, which in his view made it very possible that athletes might misuse any future drug developed in this way.[21]

If, thanks to new genetic technologies, athletes were able to block the expression of the myostatin gene and improve their production of IGF-1 or PEPCK-C, this change would be registered in their genome. The only way of identifying the change would be, at this stage, to perform a muscle biopsy, a technique which would be difficult to incorporate into regular anti-doping checks. Some athletes and coaches keep a close watch on the progress of this research into the genetic bases of sports performance. There have already been some attempts to use gene technology in sport. A German coach attempted to obtain Repoxygen, a type of gene therapy, a gene delivery vector which

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American Council on Bioethics: Transcript, Session 7: Enhancement 5: H. Lee Sweeney, Genetic Enhancement of Muscle, Friday, September 13, 2002 (http://bioethics.georgetown.edu/pcbe/transcripts).

[17] See T. Friedmann, O. Rabin, M.S. Frankel, "Gene doping and sport", *Science*, 327, 2010, p. 647-648; Robin McKie, "The drugs do work", *The Guardian Sport Monthly*, 4, February 2007.

[18] Alexandra C. McPherron, Ann M. Lawler, Se-Jin Lee, "Regulation of skeletal muscle mass in mice by a new TGF-ß superfamily member", *Nature*, 1997, 387, p. 83-90.

[19] Robin McKie reported on what Lee Sweeney had told him about being contacted by athletes. One of the first people to contact him was a sprinter asking whether Sweeney's research could help enhance his performance. "The sprinter simply wanted to know if Sweeney could do the same for him. No, said Sweeney. The techniques used to create his Schwarzenegger mice would not yet work on humans. Our complex immune systems would block his genetically engineered viruses and prevent them from getting into our cells with their IGF-1 cargo. Many more tests and trials would be needed. 'I thought I had explained it very carefully and made it clear how far away we were from carrying out gene therapy like this on people,' Sweeney told me. 'But the guy wasn't having any of it. After I had finished he said that was fine, but could I please use him as his first human guinea pig and start experimenting on him as soon as possible, please?' At that point, Sweeney hung up. Later that day there was a similar call from another athlete and the next day brought several more. By the end of the week, Sweeney had received dozens. 'I was besieged,' he says. Then coaches began ringing and what they wanted disturbed Sweeney even more. 'I took a call from one coach of an American college football team. He wanted me to inject every one of his players with the IGF-1 gene. To be fair, he did back down when I pointed out the techniques had not been tested on humans. Not every coach was that enlightened, however. Some would have quite happily tried out untested genetic enhancement techniques on all their players on the off-chance that might give them an edge over opponents.'" (Robin McKie, The drugs do work, *The Observer Sport Monthly*, 4 February 2007).

[20] M. Wenner, How to be popular during the Olympics: Be H. Lee Sweeney, Gene doping expert, *Scientific American*, 15 August 2008 (www. Scientificamerican.com).

[21] Steve Connor, "The mouse that shook the world", *The Independent*, 2 November 2007 (quoted in P. Benkimoun, Une "super-souris" aux capacités décuplées, *Le Monde*, 4 November 2007).

induces the expression of the erythropoietin gene in muscle cells.[22] A Chinese genetics laboratory offered its genetic recombination services prior to the 2008 Beijing Olympic Games. It is not known whether these gene therapy trials for enhancement purposes resulted in actual DNA recombinations and in the expression of the desired effects, but everything would seem to indicate that the arrival of these technologies in the sports world is imminent. Some gene recombination methods are simple enough that they "could be accomplished by a sharp undergrad studying molecular biology", says Sweeney. Since 2003, the World Anti-Doping Agency's Gene Doping Expert Group has funded research programmes to detect the presence of artificially recombined genes in the body or viruses used as gene transfer vehicles. But to date, no project has come up with a validated blood or urine test. Gene doping can be discovered only by carrying out a biopsy on the muscles of athletes. The day that these enhancement technologies become a reality in sport, they will be extremely difficult to detect. For doping control officers, it will therefore be much more difficult to identify the "cheats" than it is today. But doping is not necessarily cheating. It all depends on the philosophy of sport and the rules one wishes to adopt regarding the enhancement of sports performance.

3. The inefficacy and adverse effects of the anti-doping policy

WADA has developed an anti-doping ideology which is similar to the ideology underpinning the war against drugs. From the point of view of consequentialist ethics, it is far from clear that this is the best approach to adopt. Some people today believe that the eradication of doping in sport is an inappropriate solution and is bound to fail.[23] They advocate a pragmatic approach which authorises certain forms of doping under medical supervision. The members of WADA all too often tend to present the fight against doping as the fight of good against evil, without considering the merits and any adverse effects of this fight.[24] We must encourage the emergence of a public debate on the ethical and philosophical foundations of a radical anti-doping policy and reflect on the consequences of this policy on athletes' lives.[25] The following are some of the arguments that are too often overlooked in the debate on performance enhancement in sport and which question the efficacy and relevance of the current anti-doping policy.

1. The anti-doping policy is ineffective because WADA is unable to enforce the rules it lays down in the World Anti-Doping Code

"The war on doping can never be won. In doping, you can only get partial victories"

(Juan Antonio Samaranch, *New York Times*, 2 July, 2001).

The central problem with the anti-doping policy is that WADA and the sports authorities are unable to enforce the rules set out in the World Anti-Doping Code. The strengthening of the anti-doping policy from 1998 onwards has failed to curb the doping phenomenon.[26] "Scandals" have constantly come to light one after another.[27] In some disciplines, such as athletics and cycling, a large number of athletes continue to take substances despite several decades of the fight against doping. The enlightening revelations of the Austrian cyclist Bernhard Kohl – who tested positive for Cera, a second-generation EPO, in the 2008 Tour de France, following a retroactive test – show the ingenuity

[22] J.-M. Badre, Avec le Repoxygen, premier exemple de dopage génétique, *Le Figaro*, 25 August, 2009; S. Pincock, Gene doping at Torino? Evidence from a trial in Germany raises fears that athletes are already misusing gene therapy, *The Scientist*, 9 February 2006 (http://www.the-scientist.com).

[23] See, for example, the articles by B. Kayser, A. Mauron and A. Miah, Current anti-doping policy: a critical appraisal, *BMC Medical Ethics*, 2007, 8:2; J. Savulescu, B. Foddy, Ethics of performance enhancement in sport: Drugs and gene doping', R E. Ashcroft, A. Dawson, H. Draper and J.R. McMillan, (eds), *Principles of Health Care Ethics*, 2nd edition, London, John Wiley and Sons, 2007, p. 511-520; J. Savulescu, B. Foddy, "Le Tour and failure of zero tolerance: Time to relax doping controls", in R. Ter Meulen, G. Kahane, J. Savulescu (eds), *Enhancing Human Capacities,* Oxford, Wiley Blackwell, 2009; Andy Miah, *Gene Doping: A Reality, but not a Threat*, 2 May 2005, www.andymiah.net.

[24] See Verner Moller, *The Ethics of Doping and Anti-Doping*, London, Routledge, 2010; Paul Dimeo, *A History of Drug Use in Sport (1876-1976)*, London, Routledge, 2007.

[25] I concur with the view of Kayser, Mauron and Miah who state: "The ethical foundations of sport are also a matter of public debate and, like for other ethical policies in society, there should be mechanisms ensuring accountability of policy to the broader public" (Current anti-doping policy: a critical appraisal, *BMC Medical Ethics*, 2007, 8: 2).

[26] On the failure of the anti-doping policy, see the article by J. Hoberman, How drug testing fails: The politics of doping control, in W. Wilson, E. Derse, *Doping in Elite Sport*, Champaign (Il.), Human Kinetics Publishers, 2001, p. 241-274.

[27] Reference may be made in the cycling world to the Landis, Ricco, Vinokourov, Rasmussen, Contador, and Armstrong affairs, among others.

of certain athletes to avoid getting caught: carrying bags of frozen haemoglobin for autologous transfusion, bribery of WADA-accredited laboratories in central Europe to carry out illegal preventive tests, use of new, undetectable substances. Athletes who dope adapt to the testing policy. New products (EPO biosimilars, IgF1, secretagogues, etc.) turn up in the Tour de France and are already in circulation in sporting circles. In the US, the Mitchell report, the outcome of a wide-ranging investigation into doping in sport, showed that the introduction of tighter controls did not stop the taking of illicit substances, but merely led athletes to use other less easily detectable or undetectable products.[28] The USADA investigation into the US Postal Service team showed that in the year 2000 (the year where a test to detect EPO was developed), the riders had abandoned EPO and returned to blood transfusion techniques which were very difficult to detect.[29] Victor Conte, the main figure in the Balco affair,[30] had asked a chemist, Patrick Arnold, to develop for him a new undetectable synthetic steroid – THG, nicknamed "The Clear" because it meant avoiding being tested positive. Conte supplied "The Clear" to athletes and American baseball players. This substance was unknown to the anti-doping authorities until a former associate of Conte, the coach Trevor Graham, delivered a syringe containing traces of the substance to Don Catlin, director of a testing laboratory specialising in anti-doping. Conte provided top-level athletes (Marion Jones, Tim Montgomery and Dwain Chambers, among others) with doping programmes. He marked on a calendar the type of substance to take: E for EPO, G for growth hormone, I for insulin, etc. These phased programmes enabled athletes to take full advantage of the effects of the products and avoid having abnormal physiological variables. Conte "pre-tested" his athletes before competitions. He kept a record of the blood and urine results of his athletes who he regularly had tested by a private laboratory to avoid any nasty surprises in official tests. The relative inefficacy of the tests raises serious ethical issues and problems for the sports justice system. A very large number of athletes taking doping agents slip through the net. Consequently, those athletes who do not take doping agents are placed at a disadvantage in relation to those who do so secretly. This leads to the highly immoral situation in which the winner is often the "best cheat". The situation is unlikely to get any better with the arrival of biosimilars and the advent of cell and gene therapy. With regard to new drugs, there are the EPO biosimilars (official or counterfeit), EPO modulators, growth hormone biosimilars, secretagogues (which stimulate the pituitary gland producing growth hormone), the muscle growth factors IgF1 and bFGF which doping tests cannot currently detect, selective androgen receptor modulators, muscle resorption inhibitors (which work by neutralising myostatin), fat consumption activators (which target the SIRT1 gene by activating the protein PPAR-delta, AMP kinase agonists). Some of these drugs, most of which are undetectable by current doping tests are already being used by professional athletes. With regard to cell and gene therapy, the bioproduction of red blood cells from stem cells will probably expand in the near future. Cell therapy is already being used in competitive sport thanks to PRP (Platelets Rich Plasma) methods based on the fact that the platelets are rich in growth factor. Local injection of these platelets can accelerate repairs to cartilage, tendons, ligaments and muscles. These cell therapy methods may be used in sports training with the aim of maximising performance and not merely to treat injuries. Gene therapy also raises the question of misuse in high-level sport. In short, the anti-doping tools are already unable to effectively detect pharmacological doping and are likely to be completely defeated by the flood of biotechnological methods.[31] In these conditions, the aim of enabling athletes to compete "on a level playing field" is not being achieved today and will be even less so in the future. The failure of the anti-doping system based on coercive testing is plain for all to see. This is what Victor Conte, the former boss of Balco meant when he said to the British sprinter Dwain Chambers when he came to join the team of American sprinters (Marion Jones, Tim Montgomery, etc.) who were receiving Conte's doping agents: "They are cheating you, Dwain. You're a very talented athlete but you are not competing at a levelled playing field. The system allows people to cheat". [32]

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[28] *Report to the Commissioner of baseball of an independent investigation into the illegal use of steroids and other performance enhancing substances by players in major league baseball*, George J. Mitchell, DLA PIPER US LLP, 13 December 2007 (http://files.mlb.com/mitchrpt.pdf).

[29] See the appendices to the Statement from USADA regarding the U.S. Postal Service Pro Cycling Team Doping Conspiracy: http://cyclinginvestigation.usada.org/.

[30] As Director of Balco, a laboratory specialising in food supplements for athletes, Victor Conte had unlawfully set up a performance-enhancement programme for various American athletes, in particular for the sprinter Tim Montgomery, to enable him to beat the world 100 metres record. Baseball players were also implicated in this affair. See the book by M. Fainaru-Wada and L. Williams, *Game of Shadows*, New York, Gotham Books, 2006.

[31] See Gérard Dine, Le dopage sportif et son avenir, in Hottois, G., Missa, J-N., Perbal, L., *L'homme et ses préfixes. Une brève encyclopédie du transhumanisme et du posthumanisme*, Vrin, 2013, in press.

[32] Victor Conte, quoted in Dwain Chambers, *Race against me*, Libros, London, 2009, p. 61.

2. Doping is the logical consequence of the essence of competitive sport: maximising performance

The prohibition of doping introduces a structural contradiction into competitive sport. Athletes are asked to surpass themselves, but at the same time they are prohibited, on questionable grounds, from using the means that would make this possible. Doping is none other than the logical consequence of the quest to maximise performance. The nature of competitive sport encourages athletes to supplement their training with a biomedical preparation. It may seem paradoxical to seek to prohibit a practice which is at the very heart of the logic of competitive sport: to improve performances, at whatever cost. Athletes are asked to "surpass themselves" but at the same they are forbidden to use doping. It is very unlikely that anyone will in the near future beat Florence Griffith Joyner's 10.49 100m record[33] of 1988) or that a cyclist will break Marco Pantani's 36:45 record time in 1997 for the climb up the Alpe d'Huez without using performance-enhancing drugs or technology. Some records are impossible to break with a "natural" body. Clearly, the view could be taken that this quest for performance enhancement is absurd and that one should no longer seek to break records, but in so doing, we would at the same time be putting an end to competitive sport, a utopian and less than desirable objective.

3. Doping is not "fundamentally contrary to the spirit of sport": it is part of the reality, the rationale and the history of competitive sport

In the fundamental rationale of the World Anti-Doping Code it is stated that "doping is fundamentally contrary to the spirit of sport".[34] This is an untruth. Doping is an integral part of the reality, history, rationale and therefore the "essence" of competitive sport,[35] to use ontological terms. In certain disciplines such as athletics and cycling, doping is endemic. Take cycling, for example: amphetamines, corticosteroids, anabolic steroids, EPO, PFC, gene doping, etc. Each era has had its favourite substance. After the Second World War, amphetamines became the cyclists' basic doping agent. There were very few cyclists in that era who did not use amphetamines. The physical signs of taking stimulants could even play a role in the race strategy adopted by champions.[36] Doping in the jargon of the *peloton* was the "load". And many people thought the Tour de France would not really have been the Tour de France without its share of "loaded" riders. Imported from the US by American military, amphetamines became the basic doping agent for cyclists in the post-war period. They reduced the pain and increased the desire to keep on pedalling. The co-director of the Tour de France, Félix Levitan, under no illusions, wrote in a 1965 edition of the *Miroir des sports that* "anyone who doesn't do doping is a poor soul who will be beaten even before the race begins". An injection of amphetamines pushed back the pain threshold. Riders were no longer aware of their limits. They became pedalling machines, right up to victory if all went well. Until they collapsed, if an excessive "load" caused the "human boiler" to explode, as happened with Tom Simpson who suddenly collapsed in 1967 during the ascent of Mont Ventoux. In the Tour jargon "boiler" is a doped rider. Analysis of Simpson's corpse showed that the taking of amphetamines, combined with the heat, fatigue and alcohol had been the cause of death. Amphetamines were one of the most widely used drugs in the 1970s and 1980s. In his book *Nous étions jeunes et insouciants*, Laurent Fignon, double winner of the Tour de France, admits using corticosteroids and said that in the riders' jargon, "doing one's job" meant taking doping agents.[37]

Erythropoietin (EPO) first appeared in the Tour de France around 1990. EPO stimulates the production of red blood cells. Obtained artificially by genetic engineering, EPO is prescribed for

[33] On 16 July 1988, at the American trials for the Seoul Olympics in Indianapolis.

[34] The "spirit of sport" is defined as follows in the World Anti-Doping Code: "Anti-doping programmes seek to preserve what is intrinsically valuable about sport. This intrinsic value is often referred to as "the spirit of sport", it is the essence of Olympism; it is how we play true. The spirit of sport is the celebration of the human spirit, body and mind, and is characterised by the following values: ethics, fair play and honesty; health; excellence in performance; character and education; fun and joy; teamwork; dedication and commitment; respect for rules and laws; respect for self and other participants; courage; community and solidarity. Doping is fundamentally contrary to the spirit of sport." (World Anti-Doping Code, www.wada-ama.org).

[35] For a history of doping, see, for example Paul Dimeo, *A History of Drug Use in Sport (1876-1976)*, London, Routledge, 2007.

[36] Amphetamines, or "La bomba" in Italian cyclist jargon, boosted the cyclist's energy at the end of a stage, but could also prevent him from sleeping and recovering during the night. In his book *Fallen Angel. The Passion of Fausto Coppi*, an author specialising in the history of cycling writes that before one of the mountain stages in the Giro, Coppi asked one of his team members, the *gregario* Ettore Milano, to look at the eyes of his main rival, the Swiss champion Hugo Koblet. "To my immense pleasure," Milano said, "I noticed that Koblet had eyes that would scare you. At once I went to Fausto and said to him "Look Koblet has 'drunk'– his eyes are in the back of his head." "Mine are too", said Fausto." Acting on these signs, Coppi went on the attack, passing his rival on the climb up the Stelvio and won the 1953 Giro (W. Fotheringham, *Fallen Angel. The Passion of Fausto Coppi*, London, Yellow Jersey Press, 2009 ; R. Moore, *Stelvio, Rouleur, Issue Seven*, 2007, p. 40).

[37] Laurent Fignon, *Nous étions jeunes et insouciants*, Paris, Grasset, 2009, p. 89.

certain patients suffering from kidney failure on haemodialysis, or to treat severe cases of anaemia. In cycling, it has helped improve performance – once again in this shift from a therapeutic to an enhancement approach. In the 1990s and 2000s, victory in the Tour de France without taking EPO was virtually impossible. In his statement to the US Anti-Doping Agency (USADA), the former loyal team-mate of Lance Armstrong explained the circumstances in which he and Armstrong had had no other choice but to take EPO from 1995 onwards recognising that "We got crushed in the Milan San Remo race and coming home from the race Lance Armstrong was very upset. As we drove home Lance said in substance 'this is bullshit, people are using stuff and we are getting killed'. He said in substance that he did not want to get crushed any more and something needed to be done. I understood that he meant the team needed to get on EPO."[38] Interviewed by Oprah Winfrey in 2013, Lance Armstrong confirmed that if you wished to win the Tour de France you had to use drugs. He said that using banned substances was part and parcel of the cyclists' profession: "That's like saying we have to have air in our tyres or we have to have water in our bottles. That was, in my view, part of the job."[39] EPO could be used in conjunction with the older practice of autologous transfusion. Long after a course of EPO, the rider would have blood taken during the winter, when there were no controls, then would keep it refrigerated, ready to be used for competitions. The rooms of riders were like medical laboratories with a pharmacy, blood bags and microcentrifuges to test haematocrit levels. In order to be admitted into the fraternity of professional riders, it was almost mandatory to go through the initiation ritual of doping. To begin with, the newcomer with some degree of talent always believed that he could take part in cycling without doping. His body was fresh, he recovered quickly, won races and could compete even with adversaries alleged to be "loaded". But then the frequency and number of races increased and very quickly he became aware of the gap between him and those who "provided their own treatment". Gradually, he too would go down that path. First of all he would be offered innocuous substances, but which were administered by injection. This first stage made it possible to get over an initial psychological barrier since, in the mind of the young cyclist, an injection was synonymous with doping. The next stages followed on quite naturally. Since performance had been improved by a recovery substance, the next step was a simple corticosteroid tablet, on the advice of a team-mate who was adamant that it was not dangerous. To begin with there were clear benefits. But thereafter, as a result of dependence, it would be extremely hard to refuse higher doses and stronger drugs, such as steroids, amphetamines and EPO. All riders have experienced this relentless spiral. Some might have resisted longer than others but in the end all, or almost all, would have given in, in order to keep their job as professional cyclist and out of love for cycling. Clearly, doping was not officially imposed by the team. But those who did not take anything were well aware that their contracts would not be renewed. They also knew that they had no chance of being included in the contenders for the final victory. Doping is an integral part of the cycling culture.[40] To say that doping is fundamentally contrary to the spirit of sport is to deny the history and reality of sport. Doping lies at the very heart of competitive sport.[41] The nature of professional sport forces athletes to supplement their training with a biomedical preparation. We may regret this fact and live in a state of nostalgia for a "pure sport" that has never existed. But it would be difficult to deny that recourse to doping and biomedical technology is instinctively part of the performance-enhancing philosophy of high-level sport. Is it not paradoxical to want to prohibit conduct which derives from the very heart of competitive sport? Would it not be more logical to accept that the biomedical improvement of athletes is an integral part of top-level athletes' preparations?[42] In their sociological survey of the cycling world, Christophe Brissonneau, Olivier Aubel and Fabien Ohl observe that pharmacology is an integral part of the training schedule: "Without pharmacology, the pressure of training becomes impossible to cope with. The volume of training (in hours), heart rate (per minute), the gear used and the type and

[38] See the affidavit of George Hincapie in the "Appendices and supporting materials" of the Statement from USADA regarding the U.S. Postal Service Pro Cycling Team Doping Conspiracy: http://cyclinginvestigation.usada.org/.

[39] See the transcript of Opra Winfrey's interview with Lance Armstrong: http://armchairspectator.wordpress.com/2013/01/23/full-transcript-lance-armstrong-on-oprah/.

[40] The biographies or statements of cyclists or well-known figures in the cycling world will bear this out. See, for example: Erwann Menthéour, *Secret défonce*, Paris, Jean-Claude Lattès, 1999; Roger Bastide, *Doping. Les surhommes du vélo*, Paris, Solar, 1970; Paul Kimmage, *Rough Ride*, London, Yellow Jersey Press, 2001; Philippe Gaumont, *Prisonnier du dopage*, Paris, Grasset, 2005.

[41] In a quite remarkable sociological survey based on statements by cyclists, Christophe Brissonneau, Olivier Aubel and Fabien Ohl showed that doping is part of the professional cycling culture. Many cyclists take the view that doping is not cheating. Doping is merely "doing one's job" (*L'épreuve du dopage*, Paris, PUF, 2008).

[42] This is the argument put forward by Kayser, Mauron and Miah: "Elite athletes are also constituted by scientific knowledge and this is a valued aspect of contemporary sport. As such, translating doping enhancements into earned advantages – having the best scientists on one's team – would more closely align to the values of competition than leaving it all to chance, unequal access to illicit practices, and the cleverness of undetected cheating." (Current anti-doping policy: a critical appraisal, *BMC Medical Ethics*, 2007, 8:2).

dosage of the substance to be consumed are all part of the training programme. These four main parameters clearly illustrate how pharmacology is an integral part of ensuring greater efficiency of movement and the use of all possible technologies to enhance performance."[43] Maximising performance by developing through training one's natural talent and seeking out the best biomedical preparation available is a much better definition of the spirit of contemporary sport than fine sentiments and naïve generalities about the spirit of sport set out in the World Anti-Doping Code.

4. The anti-doping philosophy generates prudishness and hypocrisy in sport

The fourth argument is linked to the ambiguity of the two sets of rules: the official rules which regard doping as cheating and the unofficial rules which, in certain disciplines, oblige athletes to use doping agents. These two sets of rules create extraordinary hypocrisy.

On the one hand, the WADA officials and international sports bodies want to launch a witch-hunt against "cheats". But in practice, year after year, athletes are obliged to use doping agents if they want to remain competitive. Everyone is aware of the extent of the doping phenomenon. And yet, in public statements, there is the pretence that it concerns only a handful of bad players intent on bending the rules in order to win easy victories. In this respect, legislation on doping under medical supervision which some people advocate could put an end to the two sets of rules and make sport fairer and more transparent. In an essay entitled *L'honneur des champions*, Olivier Dazat quite rightly attacks the hypocrisy seen in doping affairs. "The *peloton* knows perfectly well who the real cheats are, and they are not the ones singled out by the public authorities. The laws of the *peloton* are unwritten, and certain aspects of the way races are run are like indecipherable hieroglyphs. The language of the riders is a dialect we do not understand. If they come out with stock phrases, or if they lie, it is because their truth is alien to us. […] There are therefore two moralities which are tragically in collision: a public morality – an angelic terrorism which, brandishing an improbable sporting ethic, grants itself the power to place athletes in detention […]. And the primitive morality of the *peloton*, based on a profoundly impure bedrock in which there is unbridled recourse to stimulants and deception. […] The type of champion our society wishes to impose would be a mindless Mr Clean pedalling frantically under the "Parnassian" ideal of sport for sport's sake. But what type of sport?"[44]

5. The boundaries between authorised and non-authorised doping are arbitrarily defined and constantly changing.

A high haematocrit can improve performance, especially in endurance sports.[45] When they won competitions in their respective competitions, Colette Besson, Lasse Viren, Kenenisa Bekele, Haile Gebrselassie, Eero Mäntyranta, Bjarn Riis, Marion Jones, Marco Pantani, Riccardo Ricco, and Floyd Landis all had a high red blood cell counts enabling them to perform particularly well. What is the difference between these athletes? Some broke the rules, others did not. Besson, Viren, Mäntyranta, Bekele and Gebrselassie remained within the authorised limits. They never broke the rules. Colette Besson, the 400m champion at the 1968 Olympics was one of the first athletes to train at high altitude to artificially raise her haematocrit. This practice has always been authorised. The long-distance runners Bekele and Gebrselassie had a naturally high haematocrit as a result of having lived in the Ethiopian highlands. The Finnish cross-country skier Eero Mäntyranta won seven medals at the Winter Olympics between 1960 and 1968. He had an advantage over his competitors in that he had a condition in which a genetic mutation caused a change in the erythropoietin receptor. This mutation resulted in an increase in the haematocrit, enabling him to take advantage of a sort of "natural doping". There were claims that Lasse Viren had received blood transfusions to become the winner of both the 5,000m and the 10,000m at the Munich and Montreal Games, a feat that not even Zatopek had achieved and which has never been repeated. However, at the time, autologous blood transfusion was not banned by the sports codes. Similarly, the hyperbaric chamber technique has not always been prohibited. This is a means of putting athletes artificially in altitude conditions, thereby helping raise their haematocrit. Besson, Viren, Bekele, Gebrselassie and Mäntyranta were never found guilty of any wrongdoing by the sports authorities. Their "doping" was deemed to be "natural" or allowed under the sports rules in force at the time they were competing. Nicknamed "Mr 60%", Bjarne Riis had been using EPO when he won the Tour de France in 1996. The test to detect EPO in the blood was not yet available. Despite belatedly confessing to this usage in 2007, Riis was allowed to

[43] Ch. Brissonneau, O. Aubel, F. Ohl, *L'épreuve du dopage*, Paris, PUF, 2008, p. 219.
[44] O. Dazat, *L'honneur des champions*, Paris, Hoëbeke, 2000, p. 6-8.
[45] The haematocrit is the percentage of the volume of whole blood that is made up of red blood cells.

keep the yellow journey and his name remains in the record book of the Tour.[46] Marion Jones, Marco Pantani, Riccardo Ricco and Floyd Landis were not so lucky. They had used EPO and other substances to enhance their performance. They were found guilty of doping with all the negative consequences that this entails in an athlete's personal life. Marco Pantani, an Italian cyclist, the most gifted climber of his generation, was disqualified from the 1999 Giro because his haematocrit had tested above the 50% threshold accepted at the time. Following this disqualification, Pantani was the victim of media and judicial persecution from which he never recovered. He suffered from depression and died alone in a Rimini hotel room in February 2004. Marion Jones, one of the greatest athletes of the 20th century belatedly admitted having taken doping agents from 1999. She was asked to hand back her five Olympic medals. In January 2008, she was sentenced to six months in prison for perjury, after denying any involvement in the Balco doping scandal. Six months in prison for denying having taken illicit substances. Floyd Landis, the former team-mate of Lance Armstrong, the seven-time winner of the Tour de France, went on to win the Tour in 2006, but his title was withdrawn because of abnormally high testosterone levels. He was stripped of his yellow jersey and was suspended from competition until January 2009. Floyd Landis's name was removed from the record book of the Tour but Bjarne Riis's name was not, even though he had admitted having committed a comparable offence. Why? These examples show the arbitrary nature of the anti-doping rules. Why punish and ruin the lives of such talented athletes as Landis, Pantani and Jones? Why consider that the naturally raised haematocrit of Mäntyranta as a result of a genetic mutation was more legitimate than the artificially raised haematocrit of Pantani or Landis? Why condemn Pantani and Landis and celebrate the victory of Mäntyranta? Every athlete can be said to be doped because every athlete's body has been artificially modified. Why allow a period spent at high altitude which results in an increase in EPO but ban its being directly injected? All athletes are doped but only some of them are in violation because they contravene the rules or laws governing sport.[47] However, these rules are not immutable; they can be changed.

6. The anti-doping policy has many adverse effects

6.1 Threat to athletes' privacy

"I feel like a criminal"

(Rafael Nadal).

Supporters of the anti-doping philosophy believe that with new and more extensive resources, doping will gradually be eradicated. Such an attitude inevitably leads to the proliferation of bureaucratic, legal and police constraints affecting professional sport; spot checks, biological passport, cryopreservation of blood samples for subsequent testing, searches in the rooms of riders, one day perhaps muscle biopsies to counter gene doping, etc. Is it reasonable to impose such constraints on athletes who devote their whole life to sport? The war on drugs in sport is a violation of athletes' privacy. Checks can be carried out at any point, before, during or after a competition and athletes are obliged to keep testers constantly informed of their whereabouts. If an athlete fails to turn up for a spot check in an 18-month period, he or she could be suspended from competitions.[48] We are seeing a clear escalation in the severity of testing procedures. WADA recently recommended night-time controls.[49] In what other sector of society would one allow oneself to subject individuals to such constraints? More thought needs to be given to the merits of treating athletes as potential criminals obliged to inform the anti-doping organisations of their every move. A revolt is gathering momentum among athletes who want greater respect for their privacy. The tennis play Rafael Nadal recently criticised the drug-testing procedure saying he feels "like a criminal". He complains of having to see

[46] In July 2008, Bjarne Riis's name was re-entered in the record book by the organisers, with a note regarding his confession. In June 2007, his name had been removed from the list of winners of the Tour.

[47] The first doping tests in the Tour de France were introduced in the early 1960s.

[48] The World Anti-Doping Code states: "Any combination of three missed tests and/or filing failures within an eighteen-month period as determined by Anti-Doping Organisations with jurisdiction over the Athlete shall constitute an anti-doping rule violation" (World Anti-Doping Code, www.wada-ama.org).

[49] "WADA recommended that "a more varied, targeted and aggressive approach to catching cheating riders be a priority for the UCI. This should include, but not be limited to, increasing the number of anti-doping tests, testing in less acceptable hours with a greater chance of detecting substances and/or methods with short detection windows" (*Independent Observers' report on the antidoping testing carried out by the UCI at the 2010 Tour de France*, quoted in S. Farrand, "Italian riders question need for night-time anti-doping tests", 30 October 2010, cyclingnews.com).

where he will be for at least an hour every day, seven days a week. In Belgium, 65 athletes filed a legal suit against WADA claiming that testing was too intrusive and broke European privacy laws.

6.2 Criminalisation and demonisation of athletes

Current WADA policy leads to the criminalisation and demonisation of athletes. In the name of the anti-doping policy and in an attempt to impose on athletes an artificial purity which, in certain disciplines, denies the historic reality and culture of sport, the sports authorities have instituted a fierce "witch hunt", an implacable, puritanical crusade which can have dire consequences for the lives of the athletes who get caught. Many athletes have been suspended, others have had to end their careers. I have already referred above to the persecution of athletes. Let me now return to the example of Pantani.[50] The Italian climber was unable to withstand the media and judicial harassment of which he was the victim following his disqualification from the 1999 Giro. It is perfectly plausible to claim that this harassment was one of the main causes of his premature death in 2004.[51] History will find it hard to remember that the 1999 Giro was won by Ivan Gotti. This event will remain the one in which Marco Pantani was disqualified, broken in full glory on the presumption of doping just 48 hours away from a final victory that was his for the taking. Overnight the champion went from hero to pariah. A champion such as Pantani certainly did not deserve to be treated so badly. I share the views of Olivier Dazat who wrote: "Marco Pantani was brought down the day before he would have crossed the finishing line of the Giro. For thirty years people had been waiting for someone like Marco Pantani, thirty years since the last victory of Charly Gaul in the 1958 Tour de France. Poor Ivan Gotti, who put on the pink jersey after Pantani's disqualification, was well aware, as were all the riders in the *peloton*, that his compatriot was not a cheat. Despite all the modern preparation methods, there was only one Marco Pantani in the race. He was the only one able to forge a gulf between himself and the others once the road started to climb."[52]

In the United States, the authorities resort to the perjury trap to put pressure on athletes suspected of doping. Any athlete who, having taken the oath, makes a false statement to a federal agent, for example, by denying having taken drugs, is liable to a prison sentence. In the US, the perjury trap is a formidable weapon for extracting statements from those involved in doping cases.[53] This is what led to the conviction of Victor Conte, the main player in the Balco scandal, which led, in its wake, to the fall of those athletes who had worked with him, in particular Marion Jones. On 5 October 2007, brought before a New York court, she admitted having used THG (a synthetic steroid manufactured by the Balco laboratory) between September 2000 and July 2001. Following her confession, the International Association of Athletics Federations (IAAF) erased all her results subsequent to September 2000, and the IOC stripped her of the five medals she had won at the Sydney Olympics. Marion Jones was given a six month prison sentence for lying to federal investigators. "No consideration was taken for the fact that she has been shamed, that she has lost her medals, that she has been brought to financial ruin. She has paid a terrible human price already,"[54] commented George Hulse, a cousin of Jones, when the verdict was announced in early 2008. In January 2010, a BBC reporter asked Marion Jones: "Was it right that you went to jail?" After a long silence, Jones replied: "I don't think it was right. My reputation, fame and fortune were lost. Learning that lesson would have benefited society more than putting me away for six months."[55]

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[50] With regard to Pantani, see the following books and documents: M. Rendell, *The Death of Marco Pantani*, London, Weidenfeld andNicholson, 2006; P. Brunel, *Vie et mort de Marco Pantani*, Paris, Grasset, 2007; Cito, Cosimo, *Il fantasma del Galibier*, Limina, Arezzo, 2010; and the seven DVD box set on the life of Pantani: P. Bergonzi, E. Vicennati, *Tutto Pantani. Una vita in salita*, La Gazzetta dello Sport & Rai Trade, 2008.

[51] An article in *Libération* published shortly after the death of Pantani gives a good account of the indignation felt by the supporters of the Italian champion: "With his blue helmet on his head, the fluorescent yellow jersey covering part of his black shorts, the octogenarian Dante wanders around the San Giacomo l'Apostolo church in Cesenatico. "They let him die" he says, full of outrage and anger. After their sadness, shock and quiet contemplation, the admirers and fellow citizens of the climber vent their anger – against the cycling federation, the media, the prosecutors accused of initiating several investigations into "the pirate" for doping. "He was persecuted," says Dante, agitated. "Doping? Everyone does it. Riders can't survive on just bread and water! Marco was the only one to pay the price"" (E. Jozsef, "Entre tristesse et colère, la ville de Cesenatico enterre aujourd'hui Marco Pantani", *Libération*, 18 February 2004).

[52] O. Dazat, *L'honneur des champions*, Paris, Hoëbeke, 2000, p. 10.

[53] See M. Fainaru-Wada, L. Williams, *Game of Shadows*, New York, Gotham Books, 2006, p. 191.

[54] L. Zinser, Judge sentences Jones to 6 months in prison, *New York Times*, 12, January 2008.

[55] Inside Sport. The Marion Jones Story, BBC, 4 December 2010.

6.3 Health risks caused by clandestine doping and paternalism

"For me everything that does not injure the health of the athlete is not doping"

(Juan Antonio Samaranch, *El Mundo*, 26, July 1998)

Anti-doping advocates quite rightly claim that doping can be dangerous to health. There have indeed been a number of fatalities brought about by doping. But in the majority of cases, these accidents have occurred in a context in which the doping agents had been prescribed unlawfully, most often by personnel with no medical training. The point is that the policy which has the eradication of doping as its aim leads athletes to take drugs illegally, without any medical intermediary, so as not to be caught out by the anti-doping police. Only the wealthiest athletes can afford to seek advice from a private doctor for their biomedical preparation. Some people today say that the legalisation of doping under medical control would have the paradoxical effect of reducing the health risks for athletes by preventing underground doping. Legalisation would bring an end to the unhealthy paternalism intended to protect athletes and prevent them from succumbing to the temptation to take certain risks. What justifies this paternalism and protectionism vis-à-vis athletes? Have they not chosen this life? Are they not informed adults? Are they not free to decide whether or not to take certain risks, having weighed these up against the hoped-for benefits? And if the risks are higher, are the possible benefits not higher too? In everyday life, both professional and private, it is both possible and legitimate, to wonder about the degree of freedom and consciousness with which individuals choose to act or not act in very different situations. But this does not mean that we have to take action claiming it is in their best interests, despite themselves, and prevent them from harming themselves when they have access to the information they need to make an informed judgment. After all, are there not significant risks in high-level sport itself, particularly in certain disciplines? Cycling, for example, is not without its dangers. There number of cyclists who have died racing or training is quite staggering.[56] The *campionissimi* Gino Bartali and Fausto Coppi have both lost a brother: Serse Coppi fell off his cycle when his wheel caught in the final sprint of one of the stages in the Giro del Piemonte in 1951 and died shortly afterwards. The brother of "*Gino il pio"* was killed in a cycling accident in 1936. So in order to protect athletes' health should we be banning sport on the grounds that it is dangerous?

6.4 Constant rewriting of sports record books

Who won the final of the women's 100m at the Sydney Olympics? Marion Jones? She was the runner who first crossed the finishing line, but in 2007 she was stripped of her title on account of doping.[57] So that is the wrong answer. Ekaterini Thanou? The Greek sprinter had finished in second place. So it is her name that appears on the official record book, but the IOC chose not to award her the gold medal because of her involvement in other doping cases. So, officially, Thanou won the 100m at the Sydney Games but has to make do with a silver medal.[58] "Who won the women's 100m at the Sydney Olympics?" is therefore a question to which there is no answer and the race is one without a winner. A similar situation occurred in the 2006 Tour de France. The American rider Floyd Landis won the Tour in July, but then tested positive for testosterone in August. A long legal process then led to his disqualification and the famous yellow jersey being awarded, in October 2007, to Oscar Pereiro who had come second. So because of the slow and complicated legal proceedings, it was more than a year later that the official winner of the 2006 was announced. "At last! This has been a long time coming, too long in fact, but now, belatedly, we have a real winner," said Tour director Christian Prudhomme. A real winner? There are few cycling and Tour fans who are ready to regard Pereiro as the real winner of the 2006 Tour. Just like the women's 100m final at the Sydney Games, the 2006 Tour de France is an event without any real winner. The possibility of retroactively convicting athletes

[56] To illustrate this, see the *List of professional cyclists who died during a race* on Wikipedia, (http://en.wikipedia.org).

[57] On 5 October 2007, Marion Jones admitted having taken doping agents prior to the Sydney Games. On 9 October she handed back her medals to the US Olympic Committee, and on 12 December the IOC officially stripped her of those medals. However, the IOC was unwilling to redistribute these medals. The IOC announced that there would be no automatic updating of the results following the disqualification of Marion Jones because other athletes could be involved in the Balco scandal. In December 2007, Jacques Rogge, IOC President said that the medals would be redistributed only if the IOC was convinced that the investigations would not reveal any new cases.

[58] In 2004, Ekaterini Thanou was one of the favourites for the 100m at the Athens Olympics. Before the start of the Games, Thanou and her compatriot, the sprinter Kenteris, failed to attend a random drugs test, claiming they had been involved in a motorcycle accident. They had already previously missed two random tests. Thanou and Kenteris withdrew from the Games. In August 2008, the executive board of the IOC barred Thanou from taking part in the Beijing Games on account of "improper conduct and bringing the Olympic movement into disrepute". In May 2010, Thanou announced that she was retiring from sport.

further reinforces the process of the constant rewriting of the sports record books. The conservation of samples taken for a period of eight years – as is authorised by the World Anti-Doping Code – and the retroactive tests which make it possible to detect at a later stage doping agents that could not be detected at the time the samples were taken are a sword of Damocles hanging over athletes. Now, you have to be patient to find out the true winner of an event. You thought that Armstrong was the seven-time winner of the Tour de France (from 1999 to 2005)? You were wrong. The anti-doping net closed in on Armstrong.[59] His fall creates a great void in the Tour record books. The 1999-2005 Tours had no winners. Victory was not reassigned to anyone. This creates considerable problems for the sports justice system. According to the sports authorities, no rider deserved the yellow jersey between 1999 and 2005. The vast majority of athletes were doping. Nobody was able to enforce the rules of the World Anti-Doping Code. This is a terrible failure of the anti-doping policy, a failure of the system which was supposed to enable athletes to compete on a level playing field without resorting to doping. The system has failed to ensure fairness. Bjarn Riis, for example, another Tour winner, was luckier than Lance Armstrong, Floyd Landis and Alberto Contador. He was able to keep his yellow jersey despite having admitted to doping when he won in 1996.[60] The anti-doping authorities are inconsistent in the sanctions imposed on riders found guilty of doping. This inconsistency is incompatible with the principle of fairness in sport. With a strengthening of the fight against doping, we are seeing a curious process of rewriting history. If we re-examine the list of Tour yellow jerseys or the winners of the 100m in the Olympics in the light of the true "spirit of sport", there is a real danger that the official record books will be full of blank pages. Should we delete whole sections of the history of sport in the name of an ethic of conviction based on the purity of the "spirit of sport"? If this process of constantly re-examining the virtue of the winners were to continue, we would end up finding that nobody, upholding the true "spirit of sport", had ever won a Tour de France or a 100m final.

7. The concept of WADA derives from a naturalistic and bioconservative philosophy

Competitive sport is not rooted in an egalitarian philosophy. Equality is far from being the central value of professional sport. Competitive sport is profoundly inegalitarian. Essentially, the athlete who wins is the one with the best genetic potential and has had the best training and medical supervision. The expression "to compete on a level playing field" is misleading. When WADA bans the use of technologies or doping agents to "promote […] fairness and equality for Athletes worldwide",[61] it is implicitly advocating a naturalistic philosophy which sees sport as the impartial arbiter of natural inequalities. In this view, being fair means respecting those inequalities. WADA therefore promotes a type of competitive sport whose role is to highlight these natural inequalities. This philosophy recompenses the most genetically and physiologically accomplished athlete, the strongest, fastest or most resilient human "animal". By defending respect for what is "naturally given", this conception is akin to the bioconservative tendency in the debate on enhancement medicine. WADA's naturalistic philosophy may at times even be transformed by the anti-doping "priests" into a veritable naturalistic religion. In this religious conception, doping becomes a genuine sin. And any athletes who engage in doping must confess in order to ensure their redemption. WADA President John Fahey states that seeing Armstrong's teammates, such as Tyler Hamilton, confess their doping past restored his faith in human nature.[62] Travis Tygart, US Anti-Doping Agency chief, believed that "riders should be given a chance to voluntarily confess and detail doping". Following their confession, repentant riders could then be "forgiven" and "pardoned" by means of a "Truth and Reconciliation" Commission.[63] In this quasi-religious conception, the fight against doping becomes a veritable puritanical crusade. Perhaps it would be more intelligent to question the validity of an anti-doping

[59] See the documents on the Armstrong affair, published by the US Anti-Doping Agency: Statement from USADA regarding the U.S. Postal Service Pro Cycling Team Doping Conspiracy (http://cyclinginvestigation.usada.org/).
[60] On 25 May 2007, Bjarn Riis admitted taking EPO during his sporting career, and in particular during the 1996 Tour de France which he had won. On 7 June 2007, his name was erased from the Tour record book, and consequently no winner's name is given for that year (1996). His name was re-entered in the record book by the organisers in July 2008, with a note regarding his confession.
[61] World Anti-Doping Code, www.wada-ama.org, p. 11.
[62] "Fahey said 'seeing cyclists like Tyler Hamilton and White confess their doping past was extremely welcome and restored his faith in human nature to see that is a sentiment that is still in sport'. 'They've at least said they're sorry and that's a step ahead of some others, who continue to deny reality' said John Fahey" (WADA to consider global amnesty for drug cheats, http://www.news.com.au/sport/more-sport/wada-to-consider-global-amnesty-for-drug-cheats/story-fndukor0-1226498924207).
[63] "Tygart said 'cycling should adopt a truth and reconciliation commission'. Tygart, and others, believe 'riders should be given a chance to voluntarily confess and detail doping'" (US Anti-Doping Agency chief Travis T. Tygart insists truth and reconciliation commission will help heal cycling, The Telegraph, 22 October 2012, http://www.telegraph.co.uk/sport/othersports/cycling/9626900/US-Anti-Doping-Agency-chief-Travis-T-Tygart-insists-truth-and-reconciliation-commission-will-help-heal-cycling.html)

policy which obliges athletes to dope – before inviting them to confess – and which constantly promises a new era of sport without ever stopping the doping phenomenon.

4. The inevitability of sport's biotechnological evolution

It is not easy to say what the best policy is with regard to doping. There are no easy solutions to this problem. But a pragmatic approach of allowing some forms of bio-enhancement under medical supervision would appear to be the most consistent with the overall philosophy of competitive sport: maximising performance. I therefore believe that the anti-doping philosophy is bound to lose ground in the years to come. It could suffer the same fate as the pro-amateurism and anti-professionalism ideology – which persecuted athletes who accepted remuneration – until it gradually died away in the 1970s when it was clear that it was becoming out of sync with the new reality of sport in a world becoming more and more open to liberalism and capitalism.

There is no one single possible attitude to doping. There is a multitude of moral theories. Ethics is certainly not the sole preserve of the advocates of prohibitionism, as is sometimes thought by certain white knights of the fight against doping, such as Dick Pound, former WADA President and my compatriot Jacques Rogge, President of the IOC, both of whom appear to think that there is only one type of Ethics, written in gold letters on Mount Olympus which prohibits any recourse to magic potions. There are other opinions and it would be mistaken to think that the prohibitionist thinkers held the monopoly of ethics. There are philosophers, sociologists and athletes who today put forward interesting arguments giving food for thought on the validity of a policy which prohibits the use of doping agents in sport. Why would a society which encourages enhanced performance in all aspects of life prohibit techniques which could further improve what athletes can achieve? And yet, we have to admit that the legalisation of doping falls short of offering a fully satisfactory solution. I have criticised the inefficacy and adverse effects of the fight against doping because today it is the official policy of the sports authorities. But intellectual honesty requires me to add that the liberalisation of doping would have its own undesirable effects. The main drawback of this stance can be stated as follows: by liberalising doping, we would oblige athletes who do not wish to dope to start doing so our give up competitive sport.[64] It also eliminates, de facto, the possibility of engaging in competitive sport without recourse to doping. The doping problem is therefore one for which there is no fully satisfactory solution. The policy, and accompanying ethical stance, to be adopted depends on the type of adverse effects one would prefer to avoid. But is this choice itself not an illusion? Above and beyond the "pro- or anti-doping" debate, it seems to me that it is impossible to prevent the arrival of certain forms of biotechnological enhancement in sport. This is also the view of Ted Friedmann, an American specialist in the applications of gene therapy in sports medicine: "So why does one think that genetic approaches to athletic enhancement are inevitable? First of all, athletes are risk-takers. They're young healthy athletes who think nothing is ever going to happen to them. And they are known to accept all sorts of risks. Polls have been taken of young athletes asking if I were to guarantee you a gold medal in the next Olympics at the risk of losing 20 years of your life would you do it? And universally, they say yes. They will take that risk for the reward of gold medals. There are enormous financial pressures and national pressures to push athletes to perform and to win. We know that they use pharmacological approaches to enhancement. We know that they're aware of gene transfer technology, and we know that that technology is still immature, but it's advancing rapidly. And we know that many of the studies in gene transfer technology, in fact, use the genes that are of particular interest to athletes, Erythropoietin, growth hormones and other relevant genes. […] enormous pressures exist in athletics which make this kind of direction very likely, and inevitable."[65] H. Lee Sweeney concurs with Friedmann. Sweeney believes that if a substance such as IGF-1 can be used safely by the general population to avoid aging-related muscle function degradation, then it would be very difficult to stop athletes taking it.[66] Moreover, what reason could there be for not allowing them to

[64] As Thomas Murray writes, "Is it not unfair to put the athletes who want to compete without drugs at a competitive disadvantage by permitting everything to tilt the playing field in favor of the drug users?" See T. H. Murray, *Sports Enhancement*, www.thehastingscenter.org; T. H. Murray, K. J. Maschke, A. A. Wasunna, *Performance Enhancing Technologies in Sports*, Baltimore, The Johns Hopkins University Press, 2009.

[65] T. Friedmann, Potential for genetic enhancement in Sports (transcript), 11 July 2002, *The President's Council on Bioethics*, www.bioethics.gov.

[66] "But, you know, if you take it away from the athletic context, which sort of muddies the whole thing, then I think of it as a preventative measure. I think if the level of safety was absolutely demonstrable that there was zero risk, then I think every person would want to be treated in this way when they're young enough so that, you know, you would never lose muscle function as you got old, I mean, assuming that you could show that there was no down side to it.

take a substance which, over and above its doping abilities, would prevent the deleterious effects on muscle function associated with aging? If we accept the reasoning of Friedmann and Sweeney, then it would appear that there is a sort of technological destiny inherent in high-level sport. Like it or not, the most probably scenario for future developments in competitive sport is that there will be increased use of biotechnological engineering to enhance performances.

If anti-doping regulations are not changed and we stick with coercive testing then there is a real risk of deadlock. The current anti-doping policy is unable to ensure fairness in sport. Its relative inefficacy results in large-scale underground doping. Legalising doping under medical supervision is an option to be looked at. What would be the worst would be for there to be no debate and that one stubbornly maintained a policy that is unable to achieve its objectives in terms of health and fairness in sport, the adverse effects of which I have highlighted above (ever growing constraints on athletes' private lives, treating doped athletes as criminals, rewriting of the sports record books, etc.). The societal choices regarding doping to be made in the future must take into account the inefficacy of the current policy and the reality of developments in biomedical techno-sciences in sport. This is part of an ethical position aimed at maximising fairness in sport and minimising the risks to the health of athletes, while at the same time preserving the interest of sports competitions.

At least from my limited viewpoint, I would see it that way, and this is what I had said and actually the popular press article that I gave you. I think if we come to a point where there's no safety issue at all and no specter of germ line transmission or anything else and all you get out of it is you stay strong as you get old so that you can get around and have a better quality of life, it would be hard for me to believe that that wouldn't then gain acceptance.
And when that gains acceptance in the population in general, then, you know, the athletic government agencies are just going to have to deal with it because whatever enhancement it provides to those athletes the public is not going to care about" (H. Lee Sweeney, Genetic Enhancement of Muscle, Friday, September 13, 2002 — http://bioethics.georgetown.edu/pcbe/transcripts).

Session 2 – Technology, intervention and control of individuals Human rights challenges

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Abstract

The current realisation that several technologies are converging, more specifically neurotechnology, nanotechnology and information technology (IT), alters our understanding of the social changes caused by these technologies and, consequently, the ethical issues they raise. This is because that convergence implies that we can no longer simply analyse these technologies separately, firstly in the light of the specific characteristics of each scientific area – neurology, biology and information science – and secondly in terms of biomedical research, followed by medical practice and, finally, non-medical uses.

Not only does this convergence result in situations so complex that they are equally complex to analyse, but also, while these technologies specifically relate to medical practices, some of them could potentially be applicable outside the field of medicine.

It appears that the issues raised from the perspective of human rights standards, such as the Oviedo Convention and the European Convention on Human Rights, relate to patient procedures whenever they are linked to medical practice, whereas they relate to monitoring whenever practices outside the field of medicine are involved.

The question will be raised of whether the extremely broad principles of these two conventions – regarding the protection of the dignity and integrity of human beings, and, in particular, the duty to obtain consent prior to any healthcare procedure as well as the right to private life – are adequate to ensure that citizens are truly protected as regards new technologies. Consideration will therefore be given to whether these “emerging” technologies should not make us consider either a new Convention similar to the Oviedo Convention – which was a remarkable development in terms of the protection of human rights – or at least an additional protocol like those which already exist.

Introduction

The new so-called emerging technologies (which are, in fact, now relatively well-established), deriving from “NBIC convergence”, which means the “integration between … biotechnology, information

technology and cognitive sciences"[67], seem not only to be opening up ground-breaking healthcare possibilities for many types of patients, but also to be offering opportunities to people who are not yet ill to use these technologies without consulting a doctor with the aim of keeping themselves as healthy as possible or even to prevent the onset of illnesses through increasingly healthy lifestyles.

At the same time, there has been a recent profusion of writing of all types on this subject. The aim of some is to describe these new technologies, generally very positively, highlighting the innovative features deriving from their convergence, and anticipating their consequences (in the short or long term) in terms of the creation of new practices and occupations[68], etc., and the emergence of new markets in which individuals are treated not so much as patients but as potential clients. Others express doubts about the possible effects of these technologies, which they often describe, if not negatively then at least critically, in terms of the transformation of social practices and the undermining of certain fundamental freedoms and legal protections.

A significant number of these assessments **focus too much on the technologies concerned** and do not take enough account of the relational context in which they are used. The most direct effect is that we are moving towards "the blurring of the line between the medical and the non-medical domain"[69], thus helping to **construct a standardised view of the political, social and ethical issues raised by the use of these different technologies**. The questions concerning the major human rights challenges posed by "intervention" and "monitoring" procedures which are addressed here are dealt with somewhat differently than they are in the abstract issued prior to the communication of 4 May 2015 as it became clear that the contrast made between "intervention", which was regarded as being specific to medical practice, and "monitoring", which was taken to relate solely to practices outside the medical sphere, was far too simplistic.

As these matters are to be addressed with reference to the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950 and the Convention on Human Rights and Biomedicine of 4 April 1997 (the Oviedo Convention)[70], it seems essential to outline the main features of these instruments before continuing. **The former** was prepared by **the Council of Europe**, whose Statute required every candidate state to accept the principles of "*the rule of law and of the* ***enjoyment*** *by all persons within its jurisdiction* ***of human rights and fundamental freedoms***"[71]. It forms "the cornerstone of the European system for the protection of human beings' essential freedoms"[72], its particularity being that it has established legal standards to "realise the aims and ideals of the Council of Europe, as expressed in its Statute, and to establish a common public order of the free democracies of Europe with the object of safeguarding their common heritage of political traditions, ideals, freedom and the ***rule of law***…"[73].

The **Oviedo Convention** stemmed from an **acknowledgment** of the "**problems confronting mankind as a result of advances in medicine and biology**"[74]. Whereas many Council of Europe member states had already adopted legal standards on the subject, the Oviedo Convention is a framework convention setting out common general standards for the protection of the human person in the context of the development of the biomedical sciences. It is complemented by three additional

[67] Van Est R., Stemerding D., Rerimassie V., Schijff M., Timmer J., Brom F., *From Bio to NBIC convergence – From Medical Practice to Daily Life*, report prepared for the Council of Europe Committee on Bioethics, Rathenau Instituut, 2014, 17.
[68] Although we are not yet really capable of properly establishing the precise parameters of these occupations and, in general, no account is taken of the potentially destructive effects on currently existing occupations.
[69] See, for example, Strand R. and Kaiser M., *Report on Ethical Issues Raised by Emerging Sciences and Technologies*, report prepared for the Council of Europe's Committee on Bioethics through the Centre for the Study of the Sciences and the Humanities, University of Bergen, 2015, p. 36.
[70] Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine.
[71] Article 3 of the Council of Europe Statute. Emphasis added.
[72] In the words of F. Moderne in *La Convention européenne des Droits de l'Homme. Texte intégral et protocoles présentés par Franck Moderne (The European Convention on Human Rights. Full text and protocols described by Franck Moderne)*, Dalloz, 2006, VIII.
[73] Austria v. Italy, 11 January 1961, application no. 788/60, *Yearbook of the Convention*, vol.4, pp. 139 et seq., http://hudoc.echr.coe.int/sites/eng/pages/search.aspx?i=001-115598#{"itemid":["001-115598"]}
[74] Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Explanatory Report, December 1996, § 1, http://conventions.coe.int/Treaty/EN/Reports/Html/164.htm

protocols, one prohibiting cloning of human beings[75], another on transplantation of organs and tissues of human origin[76] and a final one on biomedical research[77]. Unlike the European Convention on Human Rights, **it relates only to the protection of persons in the sphere of biomedical practices**. This convention, which provides "a common framework for the protection of human rights and human dignity in both longstanding and developing areas concerning the application of biology and medicine"[78], is fully in line with the European Convention on Human Rights, whose concepts it draws on.

While taking account of fundamental freedoms as enshrined both in the European Convention on Human Rights and the Oviedo Convention, our assessment will be divided into two sections, highlighting the most significant issues in each and making proposals in relation to these:
1°- the use of these technologies in a healthcare context for persons consulting a doctor because they consider themselves to be ill, i.e. a relationship governed by rules that are specific to the practice of medicine, which pursues a curative goal;
2°- the use of these technologies in a non-medical context, as proposed by operators working in the digital field, whose services have an underlying component of promoting health and preventing illnesses but are governed by the rules of commercial law and the Internet.

In conclusion, we will look into the impact of healthcare concepts underlying the use of these technologies in a non-medical context on the principles governing medical practices. These can lead to the development of both an ***objectified view of the person*** and a ***continuum between prevention and cure,*** which, while seemingly promoting personal autonomy, makes people take responsibility for their own state of health.

1. The use of these technologies in a healthcare context: persons consulting a doctor because they consider themselves to be ill

Two telling examples have been selected, namely **Deep Brain Stimulation** (DBS) because it requires an ***intervention procedure on a person*** and the **monitoring of a diabetic person** for the **purpose of therapeutic education** because it raises questions relating to ***monitoring***.

Deep Brain Stimulation (DBS) is a neurosurgical technology which has been used since the mid-1980s to treat neurological movement disorders, chiefly Parkinson's disease, for which it has become a reference treatment. It requires a surgical operation, in which a high-frequency stimulating electrode, whose activation is controlled by the patient, is implanted in a deep part of the brain. The procedure is based on the modulation of brain activity through electrodes implanted permanently in the brain. They are connected to a battery placed in the chest cavity and allow for the chronic electrical stimulation of neuronal populations. Doctors can then alter the stimulation parameters in line with the patient's symptoms and side-effects through an external control box, which is separate from the patient. Added to this is the fact that DBS requires the implantation in a deep part of the brain of an active implantable device[79] made of nanocarbon providing high frequency stimulation.

The **monitoring of a diabetic person** for the purpose of therapeutic education is the second illustration. The example chosen is a project still at the testing stage and sponsored by the French pharmaceutical company, Sanofi, called the Diabeo project. One of the representatives of Sanofi describes it in the following terms: "this is a connected health tool for diabetics, which is intended to help patients calculate their insulin doses and balance their meals by **offering advice on improvements to be made according to the shortcomings recorded**. The remote transmission of

[75] Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings, 1998, http://conventions.coe.int/Treaty/EN/Treaties/Html/168.htm
[76] Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin, 2002, http://conventions.coe.int/Treaty/EN/Treaties/Html/186.htm
[77] Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research, 2005, http://www.coe.int/t/dg3/healthbioethic/Activities/02_Biomedical_research_en/195%20Protocole%20recherche%20biomedicale%20e.pdf
[78] Convention on Human Rights and Biomedicine, Explanatory Report, § 7, http://conventions.coe.int/Treaty/EN/Reports/Html/164.htm
[79] See on this subject, the Opinion on the ethical aspects of ICT implants in the human body by the European Commission's European Group on Ethics in Science and New Technologies, No. 20, 16 March 2005.

results also strengthens the link with doctors, enabling patients to seek opinions and medical support at just the right moment through a trusted third party"[80].

Of course, these are two very different practices as the first requires an **invasive procedure** whereas the second relates to a **chronic illness requiring constant supervision.** Yet, it is **the same rules** that are **likely to apply** and ***they are those which govern the relations between patients and doctors***[81]. At all events, these are situations in which **doctors satisfy a demand**, namely that of persons consulting them because they believe they are ill[82]; it is the persons concerned who take the decision to consult a doctor on the basis of what they feel. Based on the symptoms, the doctor makes his or her **diagnosis** with the aim if not to cure the patient then at least to treat him or her. In this type of situation, **we are dealing with persons**, who, because they are in pain or suffering, **call on the assistance of a doctor**. Therefore it is **according to the rules governing this relationship that we have to reason,** even when new technologies are used.

The **first rule that may be referred to** is that in Article 4 of the Oviedo Convention, which establishes the requirements to carry out medical procedures: "any intervention in the health field … must be carried out **in accordance with relevant professional obligations and standards**"[83]; this rule refers both to doctors' functions and to the fact that the exercise of their profession is subject to specific rules, which are especially demanding in terms of scientific knowledge and clinical experience. The term "intervention" is general, meaning an action or a task, but in the medical field it also has the specific meaning of an operation.

With regard to the first meaning, this rule, in so far as it covers the doctor's essential task, namely "not only to heal patients but also to take the proper steps to promote health and relieve pain, taking into account the psychological well-being of the patient"[84], covers both acts of diagnosis, investigation or care and acts of prevention. However, seen **from the viewpoint of the second meaning**, this term describes one of the doctor's most important powers, which is to interfere with patients' physical integrity when the treatment required by their state makes it necessary to carry out an intervention on their body in the form of an invasive procedure.

Although these are two quite different practices, one entailing an invasive procedure and the other relating to a chronic illness requiring constant supervision, it is nonetheless the **same rules which apply**, namely the rules relating to **information** and **consent** whose role is to ensure the patient's autonomy[85]. It is worth reiterating that this means the right for persons to accept or to refuse the treatment proposed. These rules are set out as follows in Article 5 of the Oviedo Convention: "an intervention in the health field may only be carried out after the person concerned **has given free and informed consent to it**. This person shall beforehand be given **appropriate information as to the purpose and nature of the intervention** as well as on **its consequences and risks**".

The example of the monitoring of a diabetic person is an interesting one because it forms part of what is referred to as **therapeutic patient education**, which is a medical practice not entirely devoid of ambiguity, used in particular in the context of chronic diseases. It is intended to **prompt patients to take themselves in hand thanks to the skills they acquire through this education in order to cope with their illness.** Although the acquisition of these skills is highlighted as a means of securing patients' autonomy, it is still the case that doctors also see it as a means of improving their supervision. However, where this autonomy is sought to *facilitate adherence to the treatment*

[80] Philippe Tcheng, Director of Public Relations at Sanofi, in a presentation given on a day of events entitled "Health – when digital technology meets the new challenges of prevention" http://rslnmag.fr/post/2014/06/14/Sante-quand-le-numerique-repond-aux-nouveaux-enjeux-de-la-prevention.aspx

[81] Or other health professionals.

[82] Within the meaning established by Georges Canguilhem in Canguilhem G., *Le normal et le pathologique*, PUF, Galien collection, 1966. He showed that "it is primarily because people feel ill that medicine exists", adding that "it is always the relationship with the ill person through the intermediary of the clinic which justifies the use of the word 'pathological'", cited above, p. 156.

[83] Convention on Human Rights and Biomedicine, Article 4.

[84] Convention on Human Rights and Biomedicine, Explanatory Report, cited above, § 32.

[85] In this connection, see the Convention on Human Rights and Biomedicine, Explanatory Report, cited above, § 35: "the patient's consent is considered to be free and informed if it is given on the basis of objective information from the responsible health care professional as to the nature and the potential consequences of the planned intervention or of its alternatives, in the absence of any pressure from anyone. Article 5, paragraph 2, mentions the most important aspects of the information which should precede the intervention but it is not an exhaustive list: informed consent may imply, according to the circumstances, additional elements."

prescribed, **attempts to control individuals' behaviour are never far away**. In France, the legislator has taken care to specify that "therapeutic education … is not binding on patients and may not determine the rate of reimbursement of procedures and medicines relating to their illness"[86]. However, in a context in which ever-increasing costs are being taken on by social protection systems, there is a legitimate fear that in the short or long term reimbursement of treatment will be made to depend on strict observation of the technique in question[87].

This is an interesting example because it provides an illustration of a medical practice whereby a patient follows a treatment plan and is assisted in doing so with the minimum difficulty through telemedicine. It can also serve as a pathway to a discussion about the many fast-developing techniques on offer to individuals in the areas of health, well-being and performance.

2. The use of these technologies outside the medical sphere – various health, well-being and performance-related tools proposed by Internet operators

With a purpose **not related** this time to **illness or hence to treatment or care**, we note that there has been a sharp rise in the development of "well-being" and "health" applications which are often linked with connected devices which are "attached to the user's body" **– bringing together the biological body and the digital world**; they are provided online by Internet operators. Two points can be made regarding these: firstly, their growth prospects are considered to be exponential[88] and so they form a market with huge potential, and secondly, their many uses are being promoted with a view to prevention, as the idea has been clearly expressed that people who look after their own health will not fall ill, or at least will do so less than persons who neglect their health, and that all of this reduces healthcare costs[89].
There have been equally abundant discussions attempting to identify the social impact, while assessments by official bodies[90] have been considering ways of regulating these new practices with a view to **protecting privacy,** looking in particular at the question as to whether the existing legal rules are capable of fulfilling this objective. Two main types of question have arisen, which, although linked to the same practices, are different in nature: the first relates to what is referred to as the "quantified self" and the second to the use of the collections of usable mass data deriving from these multiple connections.

The "quantified self" is a movement, founded in California in 2007, whose aim is to promote well-being through the analysis of various lifestyle-related activities. A sensor synchronised with a mobile application into which certain events are entered tracks physical performances during these events[91].

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[86] Article L. 1161-1 of the Public Health Code.
[87] For example, an order of 9 January 2013 establishing the procedures for the coverage of positive airway pressure procedures for the treatment of sleep apnoea and related services provided that "coverage under the compulsory health insurance scheme may be reduced or discontinued where it is ***clear from the data on the use of the apparatus*** that the ***patient must be deemed not to have followed his or her treatment***". On an appeal on grounds of abuse of authority by the National Union of Home Care Associations, the Conseil d'Etat set this order aside on the ground that "the legislators' intention was to allow for the reimbursement of patients to depend on **compliance with the procedures for the implementation of these medical facilities** and services and ***not on a requirement for patients to follow their treatment regimen***", Conseil d'Etat, 28 November 2014, National Union of Home Care Associations and Others, Nos. 366931, 374202 and 374353.
[88] For example, a study published in 2003 came to the conclusion that "the mobile market (in mHealth) should represent 23 billion dollars by 2017 and cover some 1.7 billion users": study by the consultants Research2guidance, cited in the publication by the French national data protection authority, the CNIL, *Le corps, nouvel objet connecté. Du quantified self à la m-santé : les nouveaux territoires de la mise en données du monde (The body – a new connected object. From the quantified self to m-health: new territories for data collection on everyone*), Cahiers IP, Innovation & Prospective, No. 2, 2014, 28. It should be pointed out that between 2010 and 2012, the number of mHealth applications increased from 17 000 to 97 000 and that "the Internet of things will contribute to a doubling of the size of the digital universe every two years; by 2020 it could have reached 44 000 billion gigabytes, or ten times the size it was in 2013", EMC and IDC, *The digital Universe of Opportunities: Rich Data and the Increasing Value of the Internet of Things*, April 2014, http://www.emc.com/collateral/analyst-reports/idc-digital-universe-2014.pdf
[89] For example, the Green Paper on mobile health (mHealth) notes that "healthcare systems in Europe are facing new challenges such as the ageing of the population, and increased budgetary pressure" and highlights the fact that mHealth would help to make patients more responsible for their own health "through sensors that detect and report vital signs, and mobile apps that encourage them to adhere to diet and medication". And to back up this assertion, it cites "a recent WHO study (which) shows that mHealth in the high-income countries is driven by the imperative to cut healthcare costs", Green Paper on mobile health (mHealth) COM (2014) 219, final, http://eur-lex.europa.eu/resource.html?uri=cellar:0de99b25-c0af-11e3-86f9-01aa75ed71a1.0003.01/DOC_1&format=PDF , pp. 4 and 5.
[90] Particular examples are the Green Paper on mobile health and the CNIL report, *Le corps, nouvel objet connecté. Du quantified self à la m-santé : les nouveaux territoires de la mise en données du monde*, both cited above.
[91] See the description in French on a French government site: *Quantified self, la e-santé de demain ?*, http://esante.gouv.fr/le-mag-numero-9/quantified-self-la-e-sante-de-demain

The common feature of all these practices is to **record a number of variables** relating to physical activity, nutrition, weight, cardiac rhythm, sleep, mood, etc.[92] and to **monitor them permanently and comparing them to what they should be** for a better health. However, this "self-representation in figures"[93] is not just intended for oneself but also for comparison with data from other people deriving from similar quantifying processes with an obvious performance-related aim. Accordingly, everyone is encouraged to share their data.

These practices all fall within the scope of people's **private lives** and hence of **Article 8 of the European Convention on Human Rights**, under which "everyone has the right to respect for his **private** … **life**". It should be pointed that this article *is divided into two parts*. The first lists *the rights which states must guarantee to all persons* (respect for their private and family lives and their homes and correspondence) and the second limits these rights, allowing *the public authorities to interfere in their exercise* under certain circumstances. Most of the privacy issues relating to personal data raised before the European Court of Human Rights have concerned the legitimacy of the limits that a Council of Europe member state places on them[94]; by contrast, the issues dealt with in this report relate to the relationships between private parties.

This was the basis for the adoption of the **Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 28 January 1981.** These data, in so far as they are a quantified projection of the self, *are indeed personal data* because they relate *solely to the physical, physiological and psychological identity of an individual.* However, **the question is whether or not they constitute "health data"**, which enjoy special protection as sensitive data[95], processing thereof being prohibited save in exceptional circumstances prescribed by the law. In principle, the only data that falls into this category is **medical information,** in other words data deriving from an assessment made by a doctor or a health professional, that is to say information that are **the result of a diagnosis**. Cardiac rhythm and temperature are, of course, personal information but, in themselves, without having been analysed by a doctor in the light of the person's specific circumstances, that is to say without being the result of a diagnosis[96], **they do not constitute health data**.

In addition, it should always be borne in mind that these fundamental rights were provided for **with reference to data processing procedures established** in the context of **relationships between people in European societies,** whereas the **uses described take place in the context of digital connections**, which is something that is both entirely new and **takes place on a worldwide scale**. **Information collected by a doctor** on the subject of a patient whom he or she meets face to face (over a certain length of time) and kept on computer files is collected in the context of ***a relationship between persons***, involving a relation between them. However, **measurements** obtained via smartphones are received thanks to a digital connection or, in other words, a link between a ***computer and an information system*** (network, server, etc.) and ***are obtained with one click***. There is a clear contrast therefore between ***organised relationships between people*** producing information that needs to be protected vis-à-vis third parties and ***digital connections whose main features*** are their speed and the ***links they create between systems.***

The questions they raise relate in particular to the **prior notification of users:** whether it is stated for instance for what purposes these data are produced, where they are stored, whether or not they can be controlled by the users (and, especially, whether they can be erased), whether they are shared and, if so, with whom, if they can be recovered by third parties and, if so, under what conditions (and, in particular, whether the user's consent is required) and whether they can be recovered in a consolidated form and sold, which leads us to the second point below.

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[92] The aim may be to quantify a physical activity or parameter (*Runkeeper*, *Runtastic*, *Nike+, Fitbit*); to monitor eating habits through measurements of calories (*MyFitnessPal*); to monitor weight (connected scales); to follow a risk factor; or to measure sleeping times (*Jawbone*, isommeil, …), etc.

[93] A-S Pharabod, V. Nikolski, F. Granjon, *La mise en chiffres de soi*, *Réseaux* 1/2013 (n° 177), 97-129.

[94] See, for example, European Court of Human Rights, *Protection of personal data, Factsheet,* 2014, http://www.echr.coe.int/Documents/FS_Data_ENG.pdf

[95] Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 28 January 1981, Article 6: "personal data revealing racial origin, political opinions or religious or other beliefs, as well as personal data concerning health or sexual life, may not be processed automatically unless domestic law provides appropriate safeguards".

[96] See the entry under "Diagnostique" ("diagnosis" in French) by Reisler S.J. in *Dictionnaire de la pensée médicale*, ed. Lecourt D., PUF, 2004, 328-333.

These multiple personal measurements produce "**big data**"[97] or "**impersonal data**" ("données sans personnes")[98], as Antoinette Rouvroy puts it so pertinently because **these are raw data no longer linked to the people from whom they derived** and, since they have no individual significance, not covered by the rules on personal data protection. However, as they are collected on an extensive scale and in varied contexts, they form a major source of information on the behaviour of individuals and, when compiled, compared and analysed, they make it possible to draw up profiles. As a result, they **do indeed relate to persons' private lives** and place them at **excessive risk of repeated intrusions**. These big data records are so huge that they are analysed using algorithms which pose the following problems: 1) we **do not know how they** operate; (2) **many decisions which had always been taken by people up until now are now delegated to automatic systems**[99]. By interlinking, comparing and analysing billions of items of information, they make it possible to establish patterns and matches and forecast and anticipate changes. The way in which these data are collected (through sensors attached to bodies sending data continuously), and then processed, causes people and their private lives to be objectified.

Conclusion in the form of a series of questions

This report has clearly shown that **looking at these questions through the prism of legal rules brings us back to the political and social organisation of our societies**. Therefore *it is not the technologies themselves which should be the main focus* but the **context in which they are used.** The way in which it seems necessary at a given historical moment for these technologies to be regulated by law implies that the circumstances of their impact on society also need to be taken into account.

However, we have to bear in mind that the glorification of technology which permeates many people's thinking is not neutral in social or political terms and reflects the implicit idea that **technology will solve all the problems in the area in which it is planned to be used.**

The choice to focus on certain matters rather than others in this report means that a number of issues were neglected. However, while the convergence of nano, bio and ITC (or NITC) tools is capable of producing hitherto unsuspected data, it is clear that these combined analyses **should be conducted differently according to the purpose** (healthcare, prevention, research, use outside medicine, etc.). On the other hand, the ideas on which they are based are liable to alter people's ways of looking at illness and dealing with it in the short or long term, resulting in ever more intrusive forms of control over people and reducing them to nothing more than physical bodies.

To date the health field has been the domain of healthcare professionals and establishments, the pharmaceutical industry and social insurance bodies, whose aim has been to **provide care for patients.** Another concept is now emerging, which is that of encouraging citizens to adopt healthier lifestyles in order to prevent the onset of illness[100]. New partners, in short, the Internet giants, Google, Apple, Facebook and Amazon[101], offer tools which can help in meeting this objective, particularly through connected applications and devices, the **main feature of which is to provide people with direct access to such technologies without going through their doctors**[102].

Against the background in Europe of a **constant increase in chronic illnesses combined with a high level of health costs**, there is a legitimate fear that this incitement could **be transformed into**

[97] In the sense of data disseminated using telephone or computer networks.

[98] A. Rouvroy, *Des données sans personne : le fétichisme de la donnée à caractère personnel à l'épreuve de l'idéologie des Big Data (Impersonal data – the challenge posed to the obsession with personal data by big data ideology)*, http://works.bepress.com/antoinette_rouvroy/55, a paper produced for the Conseil d'Etat's annual study, focusing in 2014 on the digital world and fundamental rights and freedoms – *Le numérique et les droits fondamentaux, étude annuelle 2014 du Conseil d'Etat*, published by La documentation française 2014, 407- 421.

[99] See, in particular, Sadin E., *La vie algorithmique. Critique de la raison numérique*, Editions l'Echappée, 2015.

[100] Or even to detect illnesses before they strike. For instance, Andrew Conrad, who runs Google Life Sciences, said in an interview he gave to Le Monde that "the medicine of the future will be based on the continuous monitoring of parameters which we currently only measure from time to time" and the effect of this would be that people would be constantly monitored through their bodies, Le Monde, 24 April 2015. http://abonnes.lemonde.fr/economie/article/2015/04/24/andrew-conrad-patron-de-google-life-sciences-la-medecine-du-futur-c-est-le-suivi-continu-des-donnees-du-patient_4622055_3234.html

[101] Referred to under the acronym GAFA.

[102] Leading, for example, the American Food and Drug Administration (FDA) in 2013 to ask the company 23andMe to stop marketing its personal genome testing kits, on the ground that its sales were based on misleading advertising and the kits had not been analytically or clinically validated.

an obligation, particularly through insurance, where the level of premiums could be made to depend on proof that persons are using these tools. What is perhaps being established or at least being developed is the notion of a **continuum between the prevention and the cure of illnesses,** burdening individuals with the responsibility of preserving their health[103] and ignoring the social and environmental causes of the onset of illnesses. The inevitable consequence of these ideas will be the introduction of **individual controls** and **increasing intrusion into people's private lives**, especially if these preventive notions are combined with an emphasis on **forecasting illnesses.**

Several successive conventions have been adopted by the Council of Europe to **enhance individuals' fundamental rights** in terms of protecting both their physical integrity and their privacy. This was the aim of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 28 January 1981 and the Convention on Human Rights and Biomedicine of 4 April 1997. Although it is a crucial right, referring solely to the right to respect for privacy, as provided for by Article 8 of the ECHR, does not seem sufficient to guarantee the full protection of the citizens of the Council of Europe member states vis-à-vis the practices referred to.

Bearing in mind the debates and exchanges which took place on 4 and 5 May 2015 at the International Conference held by the Committee on Bioethics (DH-BIO) of the Council of Europe on "Emerging technologies and human rights", it is reasonable to wonder whether, in addition to "the increased application of biomedical technologies outside the medical domain"[104] owing to "NBIC convergence", these new technologies will also bring about radical changes in medical practices.

However, the question of what model to use to modify existing laws or to create new ones should not be approached in the same way for medical and non-medical practices as they are covered by different rules reflecting different types of relationships.

Medical practices are already regulated by the Oviedo Convention on Human Rights and Biomedicine of 4 April 1997. Consideration might be given to the possibility of amending it **to take account of the various technologies referred to**. Since this convention deals with various practices requiring the human body to be used as a biological resource, it might incorporate rules on the use of data deriving from people, including raw data which has not been the subject of any diagnosis. However, the aim would not be just to add rules equivalent to those of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 28 January 1981 but to think about the interaction between the biological human body and various connected tools and applications in so far as they produce data infringing privacy.

By contrast, ***this is not the case with non-medical practices***, which in principle are not covered by the Oviedo Convention. Most such cases are governed by commercial law, although this does not necessarily mean that they do not have to abide by fundamental principles. Their compliance with the latter **would be established within the framework of EU law** and would be tested in the European Court of Justice. The EU treaties now include the Charter of Fundamental Rights, Article 6 of which provides that "the Union recognises the rights, freedoms and principles set out in" the Charter, "**which shall have the same legal value as the Treaties**" and that "**the Union shall accede to the European Convention for the Protection of Human Rights and Fundamental Freedoms**" and "**fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms** and as they result from the constitutional traditions common to the Member States, **shall constitute general principles of the European Union law**".

While the Charter of Fundamental Rights enshrines the general principles of dignity, freedom, equality, solidarity, citizenship and justice, the **principle of dignity is given a particularly prominent place** as Article 1 provides that "human dignity is inviolable. It must be respected and protected" and the explanatory report on the Charter states that dignity is not just a fundamental right but also "***the real basis of fundamental rights***"[105].

[103] And the corresponding risks of discrimination.
[104] Van Est R., Stemerding D., Rerimassie V., Schijff M., Timmer J., Brom F., *From Bio to NBIC convergence – From Medical Practice to Daily Life*, cited above, p. 40.
[105] See, on all these points, Henette-Vauchez S. and Roman D., *Droits de l'Homme et libertés fondamentales*, Dalloz, HyperCours collection, 2013, pp. 182-187.

In other words, despite the absence of a convention equivalent to the Oviedo Convention concerning the use of NBIC technologies outside the medical field, **respect for human dignity** is a **fundamental right** which may pose a limit to them[106].

By way of a final conclusion it seems reasonable to make two recommendations:
1° as the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950 and the Convention on Human Rights and Biomedicine are the work of the Council of Europe whereas the Charter of Fundamental Rights was adopted by the European Union, bearing in mind the distinctiveness of the concepts at play and their intricacy, it would not be superfluous to make **a comparative study of the various fundamental rights that apply to the various issues raised in the debates of 4 and 5 May 2015**;
2° the discussion should not overlook the fact that a significant share of Internet operators are not European, which raises the **question of competition between legal systems in relation to the protection of European citizens' fundamental rights**.

[106] It was on the basis of compliance with this principle that the judgment was given by the European Court of Justice on 14 October in the case of Omega Spielhallen- und Automatenaufstellungs-GmbH v Oberbürgermeisterin der Bundesstadt Bonn, case C-36/02. The Bonn police force had prohibited Omega from marketing games whose aim was to shoot at human targets and hence to "play at killing" people because it considered this to be at variance with certain values enshrined in the German Fundamental Law, including human dignity. When asked for a preliminary ruling, the ECJ held that the Community legal order undeniably strives to ensure ***respect for human dignity as a general principle of law*** and that ***the protection of such a fundamental right is a legitimate interest which***, in principle, ***justifies a restriction to the freedom to provide services***.

Session 3 – Data collecting and processing – New dimensions
Introductory presentation: what is at stake?

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Abstract

In our rapidly changing world the evolution of science and technology is at an unprecedented scale. Emerging technologies are already at a well advanced stage and start becoming widely accessible. Moreover with the so called phenomenon of the NBIC convergence new horizons are open before the various uses of these technologies. However as the main purpose of their use is the amelioration of human life it will have a fortiori and most of the time a direct or an indirect effect on human rights and the human dignity. In order to strike the right balance between the advantages these technologies can bring into one's everyday life and the respect of the human rights careful and thorough assessments need to be done. When assessing the effects of these technologies on human rights the respect of privacy and the protection of personal data should be placed high on the agenda as the use of these technologies are accompanied with a large amount of data collection and data processing.

In order to highlight the main challenges stemming from the use of these technologies from a privacy and data protection point of view in my presentation I propose to focus on the new ways of collection and processing of personal data. Among other topics I will touch upon issues like the possible legal basis of the data processing, the necessity, proportionality and finality principles, the use of the data for different purposes, the rights of data subjects, the redress mechanism and the information of the public. I will also treat some of the data protection issues of "big data" analysis and wearable devices. As a conclusion I will invite to a reflection on viable solutions, possible recommendations and good practices for as to these technologies are used in a privacy friendly way and in accordance with European data protection legislation.

In our very rapidly changing world there is a growing need for the respect of human rights even if it represents a higher challenge than before as it seems to require the modernisation of our existing legal instruments. With the evolution of science and technology new, innovative tools, applications and services are widely available whose use effects human rights every day at an unprecedented scale. The protection of privacy and personal data figure among the rights the most effected by those technical and technological innovations. Therefore it is highly recommended to make a thorough assessment how the new emerging technologies can be expanded in a privacy friendly way. It is not to be forgotten that the right to privacy and the right to the protection of personal data guaranteed by the Council of Europe Convention 108 for the Protection of Individuals with regard to Automatic Processing of Personal Data must be respected in every circumstances.

When examining the various questions of data protection and privacy one should firstly deal with the core definitions in order to understand the nature of protection those human rights requires. The main definition of data protection is the personal data which can be defined as any information relating to an identified or an identifiable individual. Among personal data we can differentiate another category of personal data, those of sensitive data. Those are data which contain information on the individuals' racial origin, political opinion, trade-union membership, religious beliefs, health, sexual life etc. So the data which are processed by the new emerging technologies, especially in an NBIC context are most of the time sensitive data which requires additional guarantees and a special rule for data processing. A rather new type of personal data are the biometric data which are most of the time sensitive data. Biometric data are generated with the help of a special technical procedure which uses the individuals' physical, psychological and biological characteristics and serve the purpose of identification. Highly important is the definition of the purpose for which biometric data can be processed as it is solely for the purpose of identification that it may be used; every other purpose would be considered as discriminatory according the relevant European and EU legislation. One of the best examples for biometric data are the photos of an individual: according to the method used it can be either personal (2D) or biometric data (3D). The photos of an individual can only be used for identification purposes (ex: entry badges) and cannot be used for profiling, analysing discrimination, etc… The actions one can execute with personal data is the data processing as this definition refers to any operation which is performed upon personal data. The data subject is the individual to whom the personal data is referring to whereas the data controller is a person or an institution having a decision making power concerning the data processes. We can call data processor the separate entities who are acting on behalf of the data controller carrying out the processing in the manner that was requested by the controller and for the needs of the controller. Finally, in some context there is a reference to the recipient who are usually person or institutions to whom the personal data is disclosed.

We must differentiate privacy to data protection because they are not referring to the same rights or set of rights. A lot of definition can be found for privacy, one of the most common one defines privacy as the quality or condition of being secluded form the presence, view or influence of others, of being free from public attention or intrusion. We must not confuse privacy with reclusiveness, isolation, covertness, bosom, hiding or confidentiality. We can conclude that privacy is a much broader definition than the right to the protection of personal data. After all, it is referring to the protection of individuals' private sphere, the individuals' intimacy which is to be defined carefully taking into consideration one's free choice and the socio-ethical context in which it is embedded.

It seems to be evident that we are entering in a new era if we haven't already entered yet: the Digital Age. In this new era a lot argue that personal data is becoming the new currency as the economy gets digital too and the biggest asset seems to become the control over personal data. However today in this area a lack of effective control and the versatility of the ways of processing of personal data can be observed. Data controllers are gathering huge amount personal data which are collected in large data bases used for data mining and analysis, etc. for an enhanced marketing performance of the company. Some compare this phenomena to the early development of stock exchanges market and predicts the same kind of catastrophic events if not installing effective control than in the 1930s'. New ways of processing personal data is done electronically, usually in an online data processing environment, which results in the creation and management of large data bases. The new data processing techniques involves the monitoring of social network activities, consumer profiling, online advertising, big data analysis, cloud computing etc. where personal data are most of the time processed unnoticed and differently than it was processed before. The average user is unaware of the techniques of big data analysis and what consequences it will have when giving, sharing personal data online. Even privacy professionals' knowledge on big data analysis are limited. What is known is that big data analysis contains 4 phases. The first being the phase of Data Collection with the help of web tracking, cookies, super cookies, browser fingerprinting, smart grid, etc. During the second phase, Storage and Aggregation is performed and the personal data is entered in big data pools and are prepared for analysis by data management engines. It is in the third phase when the Analysis are made by different methods. The most common are the analysis with the help of algorithms, data mining, machine learning, profiling and predictive analytics. When the data is analysed comes the final phase, the Usage: in this the already analysed data is used for business analysis, reporting, predicting and estimating the performance and setting up profiles for costumers.

It is to be mentioned here that in the *White Paper on Internet of Everything* Cisco Co. has demonstrated that the market value of the Internet of everything (IoE) can be as high as $14.4 trillion. This is mainly the result of the value of benefits of connecting people throughout the world, a new, faster and more efficient way of processing data and there is also a high value attached to the fact that "everything" comes online. The following elements was identified and analysed when calculating the estimated overall market value of IoE: Asset utilization ($2.5 trillion); Employee productivity ($2.5 trillion); Supply chain and logistics ($2.7 trillion); Customer experience ($3.7 trillion); Innovation, including reducing time to market ($3.0 trillion).

However practice has shown that the usage of these new ways of processing personal data can trigger alarming concerns over the respect of privacy and data protection. In a recent case a new product for baby was offered by via telemarketing mean to a father who was unaware of its girl's pregnancy. The company made this offer based on the analysis made on the products the daughter brought lately which indicated that their consumer might be pregnant. This examples also shows that in order to avoid unpleasant surprises we would better follow the principles and legal provisions of data protection unless we want to face privacy law litigation and enforcement issues and an overall loss of the companies', institutions' positive image. Among those one of the most important is the legal basis for data processing. It is not the subject of this presentation to elaborate on this particular issue in depth, but one could establish that it is an essential prerequisite for the data processing that it has to be done based on a valid legal base. According to the EU Directive 95/46/EC the following can represent a valid legal base for data processing: informed consent, performance of a contract, legal obligation, the protection of the vital interest of the data subject, the performance of tasks of public interests or tasks carried out by government, tax authorities, the police or other public bodies, the legitimate interest of the data controller or third party under specific conditions. We must also mention that there is always a need to set special provisions for sensitive data as those data relates to the deepest spheres of one's individual characteristics, to one's own personality. In order to have a clearer view on the practical application of those legal bases the respective opinions of the EU's Data Protection Working Party (WP29) can be recommended.

After finding the right legal base for the data processing one should pay attention to the well-defined and extensively used data protection principles. Data protection principles help to avoid unlawful, secret data processing, bulk data gathering, data pooling, profiling of individuals, data mining etc… In this sense we have to bear always in mind that personal data can only be processed in a fair and lawful way. Besides, the definition of the purpose of the data processing is one of the key elements as the data processing has to be necessary and proportionate to its purpose. Any data processing outside of the original purpose have to be justified and have to be in accordance with the relevant legal provisions. Personal data should be kept to the minimum in order to avoid unnecessary, unlawful data processing and the one who is processing personal data should be responsible for its accuracy and relevance too.

The European legislation on data protection defines well the rights of data subjects. The commonly called Access Rights can be divided into separate individual rights which a data subject can exercise in relation to his/her personal data. Everybody has to have the right to be informed on every data processing in relation to his/her personal data. After being informed the right of rectification, deletion, blocking should also be guaranteed for everyone. Against the decision of the data controller two ways of appeal should be available for data subjects, one administrative and one judicial one. There are of course some exceptions when the exercise of those rights can be limited, however one should apply those exceptions restrictively. According those exceptions as set forth by the EU Data Protection Directive (95/46/EC) the rights of data subject can only be limited for the purpose of national security; defence; public security; the prevention, investigation, detection and prosecution of criminal offences, an important economic or financial interest of the state or of the EU, a monitoring, inspection or regulatory function and the protection of the data subject or of the rights and freedoms of other.

As we could see the information to the data subjects is a key requirement with relation of processing of personal data, therefore it should always be a high priority for data controllers, data providers. Without being informed on the processing of personal data the data subject cannot make adequate decisions about his/her data and cannot exercise his/her rights in relation to the processing of his/her personal data, therefore the whole data processing cannot be seen as fair and lawful. There is a lot to say about the quality and the ways of informing data subjects, but it seems to be obvious that the information shall be easily accessible, structured and easily readable. It seems to be non the less

important that it shall be available for consultation for the data subjects before the data processing begins and shall preferably contain information on the data controller, the legal basis and the purpose of the data processing. The information on data processing shall also inform about the most important issues concerning data processing such as the retention time, retention circumstances, the most important information concerning the exercise of the rights of the data subjects and rights to legal remedy.

When looking at the practice and moreover to the practice of the use of new technologies in data processing there are some challenges which need to be highlighted. One of the biggest challenges is the processing personal data for different purpose. As described above the purpose of the data processing is an important element and it is a much appreciated legal guarantee that the purpose of the data processing has to be defined in advance the data processing starts. Therefore if new (business, law enforcement, efficiency, better service, etc.) opportunities for data processing occur it always represents a challenge to process or not to process the personal data according to these new purposes. It seems to be necessary in these cases prior to all to check the legal base for the new purpose, it is essential also to inform the data subject about the new purpose and to finally to guarantee to him/her the right to object to this new data processing activity.

Another challenge is the transfer of personal data as many data controller uses data processor often operating in another or in a third country. The legal provisions for the transfer of personal data can vary from country to country, but in some cases from federal states to federal states. We can come to a conclusion that the main requirement for a legal transfer of personal data is that the recipient ensures the same level of protection and that the data subject should be adequately informed about the transfer. However we must point out that in the globalised data processing environment not every recipient, data controller, processor wish to apply the measures which would guarantee the same level of protection because of several reasons, but this results in a situation where data controllers wishing to follow the legal obligations for data transfers are facing a great challenges mainly with „non-secure" recipients, third states not being part of Convention 108 and its Additional Protocols or not applying the same legal provisions for privacy and data protection and internet clouds.

One of the major concerns for a privacy and data protection point of view when speaking of the emergence of new technologies is the big data analysis. There is a clear wish from business and even form governments to analyse the incredible amount of personal data which are available and can be easily accessible for them. With the internet, social media, smart phones, devices etc. individuals have a completely new environment for their personal data about which they don't have most of the time the necessary knowledge. Perhaps it is for that reason that it has been observed that attitude, behaviour sometimes even personality can be different to the "offline" ones. It is to be noted that there is an overall tendency to be more open and to reveal more of one's personality, thoughts, beliefs, likes, dislikes, etc. online than by conventional means. It adds to phenomenon this that users' interfaces, data collecting applications, "free" services are designed as it represents the best experience for the consumers while collecting as many data as possible without explaining the functioning and the complexity and more over the finality of the data processing. It is however evident that from the collection and analysis of personal data companies (and even governments) can make a better personalisation of their goods and services which represents for them one of the most valuable assets. It is also to be noted that when used lawfully this can be a clear advantage for customers too. In the meantime as we speak about differentiations (if not discrimination) one could establish that there are even at that phase some social, legal, ethical concerns to be faced, questions to be answered. We can also see that in those data processing systems there is an overall lack of adequate privacy and data protection guarantees. The real benefit of those systems is also unproven (for costumers), but what is it known already that the data subject is not the main winner. It is to be mentioned that big data even if it's depersonalised at one point is considered – at least by privacy professionals – as personal data. The main reason for that lies in the question of the possibility of identification. It is widely acknowledged that one can restore the link with the data subject of the raw data which is to be analysed even if it is most of the time not simple. It seems to be more evident when in the usage phase the company (data controller?) approaches the data subject with personalised offer generated on the basis of his/her personal data even if this data in the storage, aggregation and the analysis phase is depersonalised. From the classical data protection principles the one of purpose limitation and data minimisation is surely not respected and major concerns over informed consent and the exercise of access rights can be raised too. Because of the distortion of the market we can see an unfair competition between market players which have its impact on data

processing techniques and have negative effects towards the transparency too. Unclear data processing operations, lack of adequate information to data subjects, the secrecy of decision making (secret algorithms) can be observed which goes along with the lack of effective cooperation between stakeholders. Questions about techniques of anonymisation, masking techniques are open as well. Compliance to national legislation and soft law measures can be perceived as problematic too as the data protection legislations are fragmented.

The second complex and new challenge in the Digital Age is the Internet of Things. We can see that the smart devices and the wearable devices are becoming more and more popular as those devices, applications, services are to make everyone's life easier, enjoyable, and configurable. One can find a lot of joy in individualising products and services but this again involves necessarily the processing of personal data. What we can observe here (too) is when using these devices, applications, services that there is a lack of control over personal data, a rather asymmetric information flow and a lack of transparency and awareness. These new technologies amass and process of large quantities of data and usually have poor data security configuration. They process personal data in distance and data controllers use very often data for different purposes too. Most of the time those data are used for profiling, analysis and publication of behavioural patterns. Big concerns are raised about informed consent and the impossibility of using those devices, applications, services anonymously. In addition there is also a high degree of fragmentation between the players and most of the time they choose efficiency over security which gives place to even higher concerns.

In order to tackle with the variety of concerns the use of those technologies represent and to mitigate the risk of privacy intrusion, unlawful data processing, data breaches, etc. some recommendations seems to be appropriate. First of all the use of the so called privacy by design principle seems to be highly beneficial. The privacy by design principle is a well-recognised privacy and data protection principle which integrates the privacy and data protection consideration into the designing phase of the data processing activity. Data controllers, providers are choosing a user oriented approach and they integrate privacy and data protection elements into the whole life-cycle of a product or service as a default setting. As we are facing a rather fragmented market with lot of distortion and a clearly globalised functioning a top down approach would also be desirable. We would want to incorporate the application of this principle in our international and regional relations. The ideal solution would be to have this principle applied globally by governments and by market players. As a benefit of this the data controllers, processors would become more sensitive, proactive and preventive towards the protection of privacy and the personal data. It would than result to easier achieve a win-win situation which could after all lead to more trust and more transparency. Its highest achievement would be a better public acceptance, a better compliance with national, international legislation and what counts nowadays the most in an overall positive image of the data controller, provider.

Another useful tool could be the privacy impact assessment (PIA). Several European and international good examples are already available (PIAF project, Smart meter DPIA, Privacy Impact Assessment Guide by OAIC) but the extended use of this tool is more than advisable. As a general definition the PIA is a process which evaluates and manages the privacy risks the intended data processing may trigger. The PIA should, in general consist of a scheme of data flow which enables to showcase the points where the data processing can be modified and the privacy (and data protection) vulnerabilities. It contains an analysis too on the compliance of technical and legal requirements and on the level of the protection of privacy. Finally it proposes legal and technical solutions, measures to be taken for mitigating privacy risks and if privacy intrusion, data breach occurs an action plan to minimize the negative effects, consequences. A lot can be said on the methodology and the content of a PIA but the data controller or processor seems to be required to reflect in details at least on the following questions:

- Is the purpose of the data processing legal (One can have a valid legal base being the whole data processing illegal)? Does it have a valid and legal purpose?
- Does the data processing have the right legal base (One can have a lawful data processing without the proper legal base)?
- Is the data processing fair?
- Is the data processing is necessary for achieving the purpose?
- Is the data processing is proportionate in relation to the purpose?
- Is the data processing is appropriate for the purpose?
- Does it fulfil legal obligations related to data protection and data security?

- Is the PIA is well founded and responding adequately to all eventual privacy risks?
- Have data subjects been properly informed?

In final conclusion we could establish that in order to cope with the challenges the use of these emerging technologies implies for the Human Rights, especially to privacy and the protection of personal data we need to have a global and a top down approach. First of all, we must hurry up our reforms of legislations (Convention 108, EU Data package reform) in order to provide as soon as possible adequate legal framework and instruments for the new ways of data processing and the protection of data subjects' rights. In the meantime we should find viable solutions with the help of soft law and a meaningful and open cooperation among market players, stakeholders, governments, enforcement authorities. We must also encourage education, dissemination of information, public debate and the inclusion of NGOs to achieve a better social perception and to trigger more educated and informed choices of data subjects. In conclusion in the new era of Digital Age we must find new innovative ways of legal and effective protection of human rights, i.e. privacy and protection of personal data which responds to the new challenges mainly stemming from the use of the new technologies and which guarantees the same, if not better level of the protection of human rights as the existing instruments.

Session 3 – Data collecting and processing – New dimensions Ethical and societal perspectives

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Photo: Ralf Rödel

Abstract

Ethical and societal perspectives of these developments with specific reference to privacy, ownership and control

In order to assess the societal challenges of emerging and converging technologies (NBICT) with special regard to privacy, ownership and control it is not sufficient to refer to the well-known arsenal of concepts, criteria and procedures in bioethics, biolaw, and technology assessment. The reason for significantly widening the ethical and governance framework is not only the fact that the big data mega trend gives rise to an unprecedented thorough use of NBICTs. It is rather the deeper merging of science, technology, modified styles of scientific practices (like citizen science, but also open data policies) and the outright interests of some major data and financial companies which tend to result in a suspicious blurring of traditional boundaries (not only those between R&D and clinical practice, but particularly between the medical and non-medical spheres as well as between public duties and commercial interests). The all-emcompassing occurrence of a digitally driven solutionism (E. Morozov) transforms or even threatens highly appreciated values like freedom, justice, and solidarity but also societal practices like trust in sciences. Against this altered background ethical approaches rather have to address institutional designs on an utmost level than just to cope with more or less sophisticated personal data management strategies.

Session 3 – Data collecting and processing – New dimensions Human rights challenges

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Abstract

International Data Sharing and Human Rights: A Reinforcement

With the recent capacity increase of computing infrastructures and sequencing technologies biomedical research is becoming a global collaborative enterprise. Big data "omics" research promises faster, stronger, research results for the clinical benefit of patients worldwide. However, this approach remains viewed with a degree of suspicion by some within the European Community. This may be due to an overly narrow interpretation of the fundamental European right to data protection that does not sufficiently take into account other important human rights such as the "right to enjoy the benefits of scientific progress and its applications" *ICESCR* art. 15 and, the principle of the human genome as the common heritage of mankind, *Universal Declaration on Human Genome* art 1. The Global Alliance for Genomics and Health (GA4GH) is currently developing policy tools and governance frameworks for data sharing that are solidly anchored in international human rights thus providing a more nuanced, responsible approach conducive to international "OMICS" research. The proposed presentation will present the theoretical framework underpinning the pioneering approach of GA4GH. It will also discuss the organization's recent *Framework for Responsible Sharing of Genomic and Health Related Data* and its relationship with the European right to data protection.

Reinforcing International Data Sharing in Genomics with Human Rights

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A paper developed for the Council of Europe's proceedings on "Emerging Technologies and Human Rights"

Abstract

Genomic data are being generated at an unprecedented pace as sequencing costs fall. The generation and subsequent interpretation of these data, linked with other types of data sets, are leading to new knowledge, diagnostics, and therapies. But too much of these data are collected, stored, and regulated in silos – national, institutional and disease-specific. The long-term success of genomic research and medicine requires an internationally respected and workable framework that facilitates sharing of genomic and health-related data in a responsible manner. Human rights established in international law have been proposed as a basis for data sharing among researchers, including the right to benefit from the advances of science and the right to recognition for scientific contributions. The Global Alliance for Genomics and Health (GA4GH) is a non-profit international

organization dedicated to improving human health through the acceleration of data sharing. Through its *Framework for Responsible Sharing of Genomic and Health-Related Data* and specific Policies, the GA4GH has clarified the contents of these human rights in the context of genomic research, particularly with regard to the right of researchers to have access to and share genomic and health-related data.

Introduction

Advances in genetic sequencing and computing technologies make it possible for researchers to generate, store, and analyze massive genomic and health-related datasets. These datasets may include a large number of individuals, large quantities of genome data on each individual, and an increasing variety of administrative environmental and phenotypic data on health outcomes, behaviors, and environments (Chaussabel & Pulendran, 2015). Large-scale life sciences research, focusing on molecular profiles of individuals and groups that drive precision medicine, requires incredibly large numbers of samples. Research approaches like genome wide association studies require sample sizes in the thousands, if not millions, to reveal robust patterns of gene-disease correlation (McCarthy et al., 2008). Increasingly, there is recognition that the knowledge base for precision medicine, against which patients will be stratified into similar sub-populations in order to generate responsive diagnostics and treatments, must be global. For example, the range of normal genetic variation within a population affected by mass migration cannot be determined from sampling within a single country.

Data sets of this magnitude cannot be established without collaborations between researchers on an international scale (Bobrow, 2015). International data sharing in genomics can empower new knowledge discovery, new diagnostics, and new therapies. But how can its potential be unlocked? Robust datasets of genomic and health-related data also offer wide scope for inquiry; they are inherently reusable. The rights and interests of multiple stakeholders must be integrated: data generators, in recognition for their efforts; potential data users, in accessing data for new research uses; and participants, who expect their contributions to be used effectively to improve health, but in a way that promotes and protects their privacy.

Too often, genomic and health-related data collected for research purposes are collected and stored in silos: by type, by disease, by country, by institution (Knoppers et al., 2014). There is a pervasive lack of standards across these silos, limiting the interoperability of datasets. Standards are particularly lacking for data analysis and the tools used to carry it out. In research across institutions and jurisdictions, there is the added difficulty of a lack of harmonized approaches to regulation, consent, and data sharing procedures (Tassé, 2013). These procedures include national and regional requirements for privacy, ethics committee approval policies, interpretations by research ethics boards, and interpretations of data ownership. Moreover, the terms used to describe the process of de-identification vary in meaning and interpretation, making a common understanding of data privacy and security and access conditions difficult (GA4GH, 2015b: Appendix 2). Many genomic databases employ varying tiers of data access, typically through the dichotomy of open or controlled access processes. However, there is no consensus on the type of data that should go in each tier or on the conditions to be met to use controlled access data. IT security protocols differ across platforms. Limits imposed on cross-border transfers, though grounded in concrete concerns for protection and enforcement of participant privacy rights under foreign regulatory systems, restrict international data sharing (Kosseim et al., 2014). Such regulation is well intentioned, aiming to protect the proprietary and privacy interests of data generators and participants. Indeed, data sharing is not without risks. But too often data privacy law and regulation is drafted without data-intensive biomedical research in mind, and consequently many rules are disproportionate in regards to research risks. In order to realize the benefits of data sharing in health research, regulations that are overly restrictive, ineffective, or that vary widely across jurisdictions need to be modified, to be at a minimum interoperable.

These problems are only likely to worsen as researchers look to translate genomic findings into clinical applications. This will require linkage between molecular and clinical data. Linkage with health records involves further variation between standards across clinical databases. Discrepancies arise between how clinical values are recorded, as well as between the platforms and software used to store and analyze data. Different regulations apply to the release of clinical data from health systems across jurisdictions (Oderkirk et al., 2013). Even where laws are similar, interpretation of the legal conditions for data release may differ across institutions (Ritchie, 2014).

In short, the international, multidisciplinary collaboration needed for effective discovery and translation in genomics is hindered by regulatory systems that do not support cross-study or cross-border research collaboration. Failure to address these issues risks the wasteful generation of a mass of fragmented data. International collaboration in genomic research would benefit from an international framework of principles for research conduct (Knoppers et al., 2014). Such a framework would respect researcher contributions, facilitate data sharing, and ensure respect for the interests of participants. This paper reviews recent efforts to develop a framework for the regulation of international genomic research founded upon human rights.

1. A human rights framework for data sharing

There are two largely overlooked and interconnected human rights in the Universal Declaration of Human Rights (UDHR) that promote data sharing in research (United Nations, 1948). First, Article 27(1) defines the "right to science": "Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits". Second, Article 27(2) defines the "right to recognition": "Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author". In combination with other human rights recognized in Europe and internationally, including privacy, non-discrimination, and scientific freedom (Council of Europe, 1950; 2000; United Nations, 1948), these rights can form a principled and practical basis for data exchange, one that brings together governments, regulators, funders, patient groups, information technologists, industry, publishers, and research consortia.

An additional consideration in Europe is the fundamental right to the protection of personal data, articulated as a distinct element of the right to respect for private life under the *Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data* (also known as Convention 108), and given substance by the *Data Protection Directive* (Council of Europe, 1981; European Union, 1995). The right to data protection in Europe is not absolute. According to the principle of proportionality, it must be balanced against other rights (European Union Agency for Fundamental Rights, 2014). One such right that must be balanced under European human rights law is the right to the protection and promotion of health. The preamble of the *Oviedo Convention on Human Rights and Biomedicine* affirms the need for international co-operation to ensure "all humanity may enjoy the benefits of biology and medicine" (Council of Europe, 1997). Article 3 declares a right of "equitable access to health care of appropriate quality". The right to benefit from the progress of science is considered an interdependent and underlying determinant of the right to health (World Health Organisation & Office of the United Nations High Commissioner for Human Rights, 2008).

Moreover, according to the UNESCO Venice Statement, the human right to science "has acquired an increased importance in today's globalized world" (UNESCO, 2009). In 2012, the UN appointed a Special Rapporteur in the field of cultural rights to develop the scope, normative content and obligations of the State under the human right to science. This is considered particularly important in a world where "scientific innovations are changing human existence in ways … inconceivable a few decades ago" (Shaheed, 2012). Renewed interested in the human right to science arises from a number of factors:

- Science is vital to the realization of other human rights (right to health, education, adequate standard of living)
- The need to address the negative effects of globalization and eradicating poverty.
- Its relation to other traditional human rights issues: benefit sharing, ethical conduct of science, and protection of scientific freedom.
- Science and technology may create social problems or be misused to violate human rights.
- Its relation to the 'right to take part in cultural life' and the freedom for scientific activity (Shaheed, 2012).

Commentators on the right to science have also called on professional bodies of scientists across all disciplines to elaborate their role in activating this right. The American Association for the Advancement of Science (AAAS), for example, considers the rights to such a benefit across a

spectrum (2013). This spectrum includes not only the right of citizens to have access to the applications of science, but also the right of scientists to have access to data to produce knowledge and scientific applications (See Figure 1).

Figure 1: The human right to science

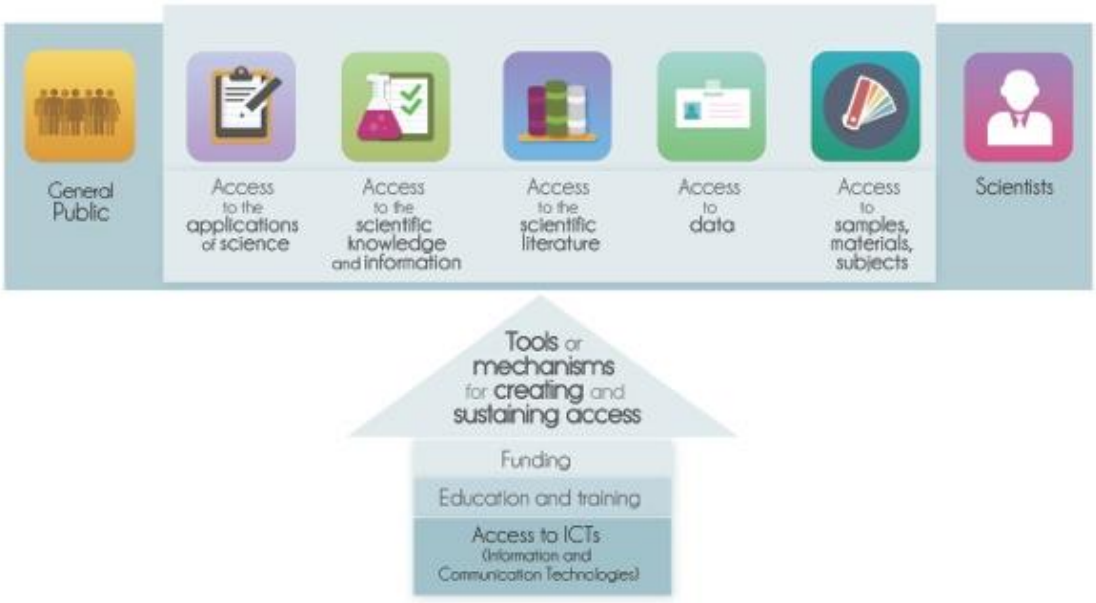

*Image based on (AAAS, 2013)

2. Why a human rights foundation?

Emphasizing a human rights foundation is promising for data sharing in genomic research for a number of reasons. First, it has universalizing force. Human rights transcend national borders or regions and apply to all human beings. Second, human rights have political and legal dimensions that reach beyond the moral appeals of bioethics. Their legal force, established in international treaties and binding on state signatories, encourages sanction through force of law if a human right is violated without compelling justification. Human rights, unlike ethical norms, demand legal monitoring and enforcement. Third, many human rights can accrue to groups in addition to individuals, reflecting the reciprocity that exists within patient communities (Knoppers et al., 2014).

Indeed, the human rights of the UDHR – including the right to science and the right to recognition – were rendered legally binding under Article 15 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), which requires State Parties to "recognize the right of everyone:

> (a) To enjoy the benefits of scientific progress and its applications;
> (b) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author" (United Nations General Assembly, 1966).

To date, 164 States have ratified the ICESCR (United Nations, 2015). They are bound to implement the treaty in their national laws, to take all steps "necessary for the conservation, the development and the diffusion of science and culture", to achieve the full realization of the right (ICESCR, Article 15(2)).

The standards and codes of professional societies that outline the ethical scientific conduct of science are also an important determinant of data sharing practices. Existing professional codes however, are primarily concerned with the ethics of individual conduct and do not place the scientific enterprise in a broader social context (Chapman, 2009). Indeed, as the UN Special Rapporteur points out, few such codes of ethics are explicitly based on or refer to human rights (Shaheed, 2012). At a minimum, researchers are responsible for promoting the international development of science, nurturing cultures of scientific responsibility, and increasing awareness of the human rights implications of science and technology (American Association for the Advancement of Science, 2013). Responsibility for realizing

the human right to science may also extend beyond states and researchers. Regulatory frameworks developed by states to meet obligations under human rights treaties direct the behavior of private individuals and organizations. A human rights foundation can make an important contribution to establishing universal norms, in part by bridging the responsibilities of the public, academic, and private sectors to facilitate genomics research.

Despite the implications of a "right to access and use data", a human rights foundation is more balanced and proportional than absolute. A human rights foundation includes a range of interdependent human rights, not only a right to medical benefits or researcher recognition. The scope of the right to science is delineated by other fundamental rights, including scientific freedom (ICESCR Article 15(3) requires states to undertake to respect the freedom indispensable for scientific research and creative activity), anti-discrimination and fair access, and procedural fairness. Article 15(4) of the ICESCR also emphasizes the importance of international cooperation, requiring states to recognize "the benefits to be derived from the encouragement and development of international contacts and co-operation in the scientific and cultural fields." International collaboration is increasingly seen as an imperative for genomic research, as reflected by the mandate of the "BRCA Challenge". This international research endeavor looks to determine the range of normal and pathogenic variants of breast and ovarian cancer genes across an international population, recognizing that not even large national databases are adequately representative of the normal variation within human populations (Human Variome Project, 2015). Similarly, a global research network – MalariaGEN – was established to enable sharing of genomic epidemiological data on malaria, in order to overcome the challenges of sample collection in developing countries, as well as genetic and environmental diversity across affected populations (Achidi et al., 2008).

3. Data sharing in genomics

Data sharing to facilitate discovery and translation of findings has been an important norm in many scientific disciplines for decades (and for some, centuries) – and has long been a core feature in "omics" research. Indeed, the Bermuda Principles of 1996 set out rules for the rapid and public release of DNA sequence data. The Fort Lauderdale Statement of 2001 recognized the importance and success of the policy put forward in the Bermuda Principles, and the attendees recommended that the practice of rapid, open data release be extended to apply to all sequence data. In 2009, the Toronto Statement developed a set of suggested best practices to promote data sharing for funding agencies, for scientists in their different roles (whether as data producers, data analysts/users, and manuscript reviewers), and for journal editors.

The Global Alliance for Genomics and Health (GA4GH), an international non-profit organization, has developed a human rights foundation for data sharing in genomic research. The GA4GH aims to accelerate progress in human health by establishing a framework that enables effective and responsible sharing of genomic and clinical data (GA4GH, 2014a). As of July 2015, the GA4GH has over 330 institutional members in 33 countries, including universities, academic medical centers, patient advocacy organizations, research consortia and associations, funders, as well as life science and IT companies.
Current bioethics frameworks for health research are founded on the principle of protection from harm. In contrast, the GA4GH has developed a *Framework for Responsible Sharing of Genomics and Health Related Data* ("Framework") (GA4GH, 2014b) that aims to activate the right to science and the right to recognition for scientific production through responsible data sharing (Knoppers et al., 2014). The GA4GH is developing actionable policies and tools to address specific issues and provide concrete guidance to researchers, clinicians and the broader research ecosystem.

To this end, the GA4GH's Framework establishes Foundational Principles for responsible research conduct and oversight in genomic and health-related data sharing. It recognizes that the twin human rights "to benefit from" and "to be recognized for" must be considered in combination with more firmly established rights of privacy and non-discrimination. The Framework is centered on four Foundational Principles: 1) Respect Individuals, Families and Communities; 2) Advance Research and Scientific Knowledge; 3) Promote Health, Wellbeing and the Fair Distribution of Benefits; and 4) Foster Trust, Integrity and Reciprocity. These Foundational Principles are further elaborated by 10 "Core Elements": transparency; accountability; engagement; data quality and security; privacy, data protection and confidentiality; risk-benefit analysis; recognition and attribution; sustainability; education and training;

and accessibility and dissemination. The Regulatory and Ethics Working Group (REWG) of the GA4GH continues to build on the Framework's Core Elements through development of specific Policies concerning accountability, privacy and security, and consent, among others. These Policies are intended to establish benchmarks and best practices for data sharing, while respecting the global diversity of ethical and legal contexts.

There is a unique benefit to situating a responsible data sharing framework within human rights. A human rights foundation can respond to key challenges faced by genomic research. As sharing and reuse of data expands, and is facilitated by the establishment of bioresources and data repositories, recognition for scientific contributions becomes fraught with complexity. Here, the right of data users to have access to genomic and health-related data must also be responsive to the right of data generators and curators to be recognized for their essential contributions. In response, the Framework holds that data systems should be designed that "provide due credit and acknowledgement of all who contributed to the results", which in turn requires that connections to the original sources of data are maintained. Other efforts in this vein include the Citation of BioResources in journal articles (CoBRA), a citation system for improving recognition of the contributions of genomic biobanks in publications (Bravo et al., 2015).

Free and informed consent is also a widely recognized prerequisite for ethical health research (Council of Europe, 1997). Furthermore, European data protection laws often require the consent of the data subject for cross-border transfer. As the perceived value of human genomic data and international sharing increases, respect for individual participants deserves renewed attention. Thus, the GA4GH's Consent Policy outlines best practices for consent to international data sharing (GA4GH, 2015a). It provides guidance for both prospective and retrospective research. Prospective research should be designed to enable broader uses and sharing of data. The Consent Policy recommends that consent forms refer to "a data sharing plan [which] has been developed and approved by a competent body". For sharing of legacy data, the Policy provides guidance for determining whether or not the original consent allow for international data sharing. Where consent is not sufficient, data sharing can only proceed with re-consent or notification with an opt out, or of consent waiver by an authorized body.

Respect for participants also means respecting their privacy, which itself is a fundamental human right (Council of Europe, 1950; 2000; United Nations General Assembly, 1948). New technologies for data generation, storage, sharing and analysis, along with the growing size and global scope of data sharing, create new challenges for privacy. Inadequate privacy and security protections compromise both participants and research, the latter of which relies heavily on the trust of participants. In response, the GA4GH has developed a Privacy and Security Policy that recognizes the fundamental importance of privacy in genomic research endeavours (GA4GH, 2015b). The Privacy and Security Policy aims to "guide and facilitate the sharing of data in a way that promotes and protects privacy and security in a proportionate manner". Safeguards "should be proportionate to the sensitivity, nature, and possible benefits, risks, and uses of the data." This proportionate approach to privacy reflects the realities of the internet age. Health researchers cannot network and collaborate effectively while simultaneously ensuring zero privacy risk. It also reflects the wishes of participants, who expect their contributions to be used not only responsibly, but also effectively. To achieve this balance, privacy risk assessments should focus on "reasonably likely harms, which may include individual or group discrimination or stigmatization" (GA4GH, 2015b).

The GA4GH's REWG has a number of ongoing initiatives addressing other emerging challenges to international data sharing in genomic research and clinical practice. For example, an Accountability Policy is currently being developed to provide a workable, meaningful, international system to ensure the accountability of data producers, users and other stakeholders involved in complex data sharing activities. This includes accountability for respecting the wishes of research participants to have their data shared. An "Ethics Review Equivalency" task team is developing models to allow for mutual recognition of ethics review processes across jurisdictions in data-intensive research. Mutual recognition in the context of international research collaborations will require harmonization of principles, forms, IT platforms and operating procedures. Shared processes are needed for ethical evaluation and oversight for a given research type. There must also be latitude for local interpretation (Knoppers, 2014). Lastly, a Machine Readable Consent task team is exploring techniques to link consent information to data sets, to make these data sets "policy aware". This will allow data users to easily assess whether a given use is authorized, ideally through an interoperable, automated,

machine-readable process.

Conclusion

Where physical risks to participants are involved, bioethical frameworks that emphasize the protection the autonomy of the participant are central. Genomic data sharing, however, involves primarily informational rather than physical risks. In this context, human rights, with their universalizing legal force, can provide an effective foundation that integrates the rights of participants, data generators and potential data users in genomic research. Data sharing must be effective, but it must also be responsible, ensuring appropriate and proportional protections for privacy, a fair and inclusive process for science, and a just distribution of the benefits of genomic research.

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Session 4 – Equity of access
Introductory presentation: what is at stake?

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Abstract

Issues concerning equity of access related to new emerging technologies and their convergences – the case of nanomedicine

"If the most severe contemporary global ethical issues are the major disparity between the standard of living in industrialized and developing nations and the socio-economic inequities within countries", write Salamanca-Buentello and Daar, "then the global community has the responsibility to judiciously harness promising tools such as nanotechnology to address the priorities of vulnerable populations, especially in the developing world, while simultaneously preventing a nano-divide".[107]

The authors do not address the issue in which order of priority the different possible tools should be put to make this come true. On the contrary, they seem to hold the view that nanotechnology is a tool on equal footing with tools we already today know would be effective in fighting these disparities and inequities if there was sufficient political will in the world to make use of them.

From the vantage point of Article 3 of the *Convention on Human Rights and Biomedicine* on 'Equitable access to health care' and Article 15 of the *Universal Declaration on Bioethics and Human Rights* on 'Sharing of benefits', the case of nanomedicine will be discussed, with a view to addressing the question *whether*, *how* – and eventually – *to what extent* nanomedicine can contribute to narrowing the health disparities gap *between* industrialized and developing nations as well as reducing health inequities *within* countries.

"If the most severe contemporary global ethical issues are the major disparity between the standard of living in industrialized and developing nations and the socio-economic inequities within countries", write Salamanca-Buentello and Daar, "then the global community has the responsibility to judiciously harness promising tools such as nanotechnology to address the priorities of vulnerable populations, especially in the developing world, while simultaneously preventing a nano-divide".[108] *The authors do*

[107] Fabio Salamanca-Buentello and Abdallah S. Daar, 'Dust of Wonder, Dust of Doom: A Landscape of Nanotechnology, Nanoethics, and Sustainable Development', in Bagheri A, Moreno J and Semplici S. (Eds.), *Global Bioethics. The Impact of the UNESCO International Bioethics Committee*, Springer 2015 (forthcoming).

[108] Fabio Salamanca-Buentello and Abdallah S. Daar, 'Dust of Wonder, Dust of Doom: A Landscape of Nanotechnology, Nanoethics, and Sustainable Development', in Bagheri A, Moreno J and Semplici S. (Eds.), *Global Bioethics. The Impact of the*

not address the issue in which order of priority the different possible tools should be put to make this come true. On the contrary, they seem to hold the view that nanotechnology is a tool on equal footing with tools we already today know would be effective in fighting these disparities and inequities if there was sufficient political will in the world to make use of them. From the vantage point of Article 3 of the Convention on Human Rights and Biomedicine on 'Equitable access to health care' and Article 15 of the Universal Declaration on Bioethics and Human Rights on 'Sharing of benefits', the case of nanomedicine will be discussed, with a view to addressing the question whether, how – and eventually – to what extent nanomedicine can contribute to narrowing the health disparities gap between industrialized and developing nations as well as reducing health inequities within countries.

Introduction

The application of emerging technologies like nanotechnology in the field of health is profiled as one of the most promising, and nanomedicine has been an important part of nanotechnology from the very beginning. Nanomedicine is based on molecular knowledge of the human body and it involves molecular tools for the diagnosis and treatment of disease. Nanomedicine, in other words, is disease-centered, trying to do better on a molecular level what physiology, pathology, and the various specialised medical sciences have been doing so far.[109]

Characteristic of these emerging technologies is that they are not yet well established, hugely funded, and ride on a wave of broad public support. As stated by Invernizzi and Foladori: "it is quite possible that in the coming decades, significant changes in human life and society will take place as a result of nanotechnologies. Some of the most promising applications lie in the field of nanomedicine. Scientists are talking about faster and more accurate ways of diagnosing disease, new ways of targeting drugs directly to the diseased cells or organs and the regeneration of organs, bones or teeth, using a patient's own tissues. On the whole, these technologies promise to lengthen the human lifespan and reverse the effects of ageing".[110]

Another characteristic of these technologies is that experts are more concerned about risks than the public. To give expression to such concerns 'ethics' has become a lingua franca – a kind of forum in which all stakeholders come together to share their concerns. The language of concern serves as a kind of soundtrack or ongoing chatter that accompanies 'responsible development'. And still**,** emerging technologies like nanotechnology and nanomedicine are pictured as frail plants that could wither and die if we aren't really careful and attend to its impacts. Accordingly, every report about societal implications concludes that more research is needed on societal implications – whatever these may be.

Nanotechnology and nanomedicine - the global dimension

In a paper published in 2005[111], nanotechnology is promoted as the solution to many problems in developing countries. After interviewing 63 experts in nanotechnology from several developed and developing countries, the authors identified the ten main nanotechnologies that could provide a solution to such problems as water, agriculture, nutrition, health, energy and the environment. The technologies range from energy production and conservation systems, with sensors that will increase agricultural productivity and the treatment of water, to the diagnosis of diseases. In the paper the creation of a Global Fund is proposed for the development of these technologies for all developing countries. "Overflowing with good intentions, the proposal reflects the mechanical idea that if a problem can be identified correctly, all that has to be done is apply a suitable technology and it will be solved. Most of the examples used do not take into account that the relationship between science and society is much more complex".[112] Furthermore, the authors fail to account for the cultural, institutional and social barriers that might hamper the implementation of such technologies possible.

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Equitable access to new emerging technologies

A starter for the equity of access part of this presentation is the following question: *Why is there a need for developing a sustainable ethics of benefit sharing in scientific research and development, so as to safeguard equitable access to new emerging technologies?* Two normative answers will here be suggested, followed by a factual answer. The first answer reads as follows: There is a need for developing a sustainable ethics of benefit sharing in scientific research and development because article 15 of the Universal Declaration on Bioethics and Human Rights says so! All 192 Member States of the UN family have committed themselves to following the normative principles laid down in this Declaration. Article 15 on benefit sharing states:

> «Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, *in particular with developing countries*" (Article 15, para 1, emphasis mine).

The second normative answer relates to the *Preamble* of the Convention on Human Rights and Biomedicine which reads:

> "Affirming that progress in biology and medicine should be used for the benefit of present and future generations; Stressing the need for international co-operation so that all humanity may enjoy the benefits of biology and medicine".

In addition comes Article 3 of the Convention, on *Equitable access to healthcare*, which states: "Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality".

The third answer to the question above, i.e. the *factual* answer, goes as follows: There is a need for a sustainable ethics of benefit sharing because there exists a monstrous inequity in the world with respect to who's diseases and needs are favoured in ongoing or planned research for health programmes. To substantiate this claim I suggest to turn the attention to some disturbing facts about the normative state of affairs of international medical and health related research. Fact 1: *The 10-90 gap*. [113] Since 1996 the global community of research policymakers, researchers and bioethicists have been aware of the so-called 10/90 gap in medical and health-related research. This metaphor was introduced to depict the monstrous inequity in the world with respect to who's diseases are favoured in ongoing or planned research programmes. In concrete terms this means that at least 90% of the economical resources spent annually on medical and health related research are targeting the health needs of the richest 10% of the world's population, something which implies that the needs of 90% of the world's population have to be met from the remaining 10% of research funding. Fact 2: *The so-called globalization of clinical research*. Figures from recent empirical studies give reasons to believe that this gap has not diminished, although during the last 20 years the number of people from poor and low-income countries enrolled in clinical trials has substantially increased.[114] Evidence from these studies suggests that during this trial period the relative availability of new drugs to populations in poor- and low income countries has not increased, while the gap between wealthy nations and poor- and low-income countries with regard to who benefits from the advances of clinical research and development continues to widen.[115] What has then led to this dramatic shift in the location of clinical trials? Here are the answers from Glickman, Hutchison et al's study published in New England Journal

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in 2009:[116] First answer: *Cost savings*: substantial cost-savings may be achieved by moving phase 2 and phase 3 trials to places such as India and South America. Second answer: *Time saving:* Time costs accounts for 50% of costs to develop new drugs. Globalization of clinical trials may shorten the timeline for clinical testing and thereby the costs. Third answer: *Easier access:* Easier access to potential research participants in countries such as China and India helps to speed up the recruitment process. Fourth answer: *Fewer regulatory barriers* in poor and low-income countries help to facilitate the conduct of clinical trials for pharmaceutical and device companies. Fifth answer: *The rise in regulatory barriers and concomitant costs* in wealthy countries speed up the outsourcing of clinical trials to poor and low-income countries. These facts about the globalization of clinical trials makes it justifiable, I believe, to say that international research today is not only carried out in a global climate of gross "background injustice";[117] by the *concerted action* of powerful stakeholders in the affluent parts of the world international medical and health-related research contributes in itself actively to maintaining this injustice instead of reducing it. Fact 3: *The TRIPS regime.* Although the existing intellectual property regime for pharmaceuticals, i.e. the so-called TRIPS regime (Trade-Related Aspects of Intellectual Property Rights), is presented as the most efficient and cost-effective way of promoting medical innovations, it is for several reasons "morally deeply problematic", to use Thomas Pogge's wording.[118] In order to give weight to his argument Pogge invites the reader to participate in a tentative assessment of the effect of this regime on the four main affected groups, i.e. (1) the pharmaceutical industry and their researchers and shareholders, (2) actual and future patients in the affluent part of the world, (3) generic manufacturers of medicines and (4) actual and future patients in poor and low-income countries (p. 9). The result of his assessment is hardly surprising. The first group of stakeholders benefit grossly from the global enforcement of this regime, while the effect on the second group, i.e. actual and future patients in the affluent part of the world, is less clear-cut:

> "On the one hand, they lose opportunities to buy cheaper unlicensed versions of the medicines they need. On the other hand, through strengthened incentives toward pharmaceutical innovation, they can look forward to more rapid pharmaceutical innovation resulting in a superior arsenal of medical interventions available to them" (p. 10).

For the third group of stakeholders, on the other hand, the present regime represents a substantial infringement upon their possibilities of producing cheaper versions of patented drugs, something which in its turn reduces the access possibility of cost-saving-oriented patients in the affluent part of the world as well of patients in poor and low-income countries to cheaper and/or affordable medicines (p. 10). Finally, for the group of stakeholders most in need the TRIPS regime is undoubtedly "socially harmful" in a dramatic way: "Millions of deaths from AIDS and other treatable or curable diseases", says Pooge "are due to the suppression of manufacture and trading of generic drugs" (p. 10). Taking into account that the TRIPS regime represents an initiative from democratic governments in the affluent parts of the world and enforced upon the global community in ways that do not comply with the principles of transparency and "dominance-free dialogue", to use Jürgen Habermas' famous conception, it is due time, I believe, to state that these governments – because of their unwillingness to change this regime - should be held accountable for lending support to gross human rights violations in the name of medical and health related research. Or to formulate this statement from the vantage point of the narrative of the Tower of Babel: The language of the TRIPS regime is not a genuinely universal normative framework that makes everyone an inhabitant of the global city; on the contrary its effect is that large numbers of the poorest communities and peoples in the world fall apart, and outside the possibility of accessing the fruits of medical innovations. Thus it becomes clear that the market economic language of the TRIPS regime gives voice to the medical interests and needs of the most powerful inhabitants of the global city; and notably at the cost of essential medical needs of millions of the poorest inhabitants of the same city.

To sum up this account on equity of access: There is a need of grounding our duties in international clinical research within a *broader* normative framework of social, distributive and rectificatory justice.[119] Second, there is a need for a human rights based approach in international research, and third, there is a need to "do research *fairly* in an *unjust* world".[120]

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116 For this study, see note 4 above.

117 Ballantyne A, How to Do Research Fairly in an Unjust World, The American Journal of Bioethics, 2010, 10; 6: 26-35.

118 POGGE T, Intellectual Property Rights and Access to Essential Medicines, Policy Innovations, 2007 <http://www.policyinnovations.org/ideas/policy_library/data/FP4>.

119 London AJ, Zollman KJS. Research at the auction block. Problems for the fair benefit approach to international research. Hastings Center Report 2010;40:34–45.

120 Ballantyne, 2010.

The language of equitable access to new emerging technologies, must, in order to become not just rhetorical word-play be able to overcome the different barriers that hinder equitable access to new emerging technologies. Among these are financial barriers, scientific illiteracy, geographical barriers, language and cultural barriers, discrimination, racism, gender bias, social exclusion and unrest. In addition, social determinants of health have to be observed to make such a language function in an unjust world. Among these determinants count income and social status, education, physical environment, employment and working conditions, social support networks, genetics, personal behaviour and coping skills, and health services – access and use. In other words, if justice requires providing equitable access to the benefits of scientific research and development, then these barriers and determinants must be addressed as a matter of justice.

Equity of access – the case of nanomedicine

This brings us finely to the case of nanomedicine and the question of equitable access to this new emerging technology. At first glance, two questions seem of particular importance to pose: How could nanomedicine benefit poor and low-income countries? And, second, what could be a fair and equitable model to distribute the benefits among them? The first question cannot be adequately answered without first providing answers to four other questions: 1) What does benefit here mean? 2) Who has to define what benefit here entails? 3) Who has to define the reach of it? 4) Who decides what is good for whom? Here is a list of fundamental factors that affect the health of communities and people in poor and low-income countries, and which need to be observed in order to be able to answer these questions:

- maternal mortality
- child mortality
- infectious diseases
- malnutrition, and
- chronic illnesses

If these are the factors that fundamentally affect the health of people living under a climate of gross background injustice, then it may be that the right question to pose is not, "How can nanomedicine be made able to help in a sustainable way the development and health of populations in poor and low-income countries?". Instead, the questions should - in order of priority - be:

- What are the most frequent causes of death and disease in this country or region?
- What are the prevalent illnesses?
- How are they related to social determinants of health?
- What are the basic health needs of this community, and what are the cheapest and most sustainable ways of satisfying them, and to fight against the disease?
- *Finally*, *if nanomedicine is into the list of answers, the next question should be: will people have access to this technology in an equitable way?*[121]

An additional observation made by Susana Vidal reads as follows:

"To answer the question how could nanomedicine benefit poor and low-income countries; we need to reorganize the agenda, and propose new questions, because the questions are posed in a wrong way, and we are trying to answer them in a desperate way. We lose our time trying to answer the wrong questions".

The principle of benefit sharing revisited

I will end this presentation with some reflection on the implications of pursuing the principle of benefit sharing laid down in article 15 of the Universal Declaration of Bioethics and Human Rights. First implication: Even when biomedical research in general and nanomedicine research in particular is conducted in affluent countries in Europe and in the US these Member States of UNESCO have committed themselves to sharing the benefit of this development, "with society as a whole and within the international community, *in particular with developing countries*" (emphasis mine). Second

[121] Susana Vidal, presentation at a workshop on Nanomedicine, Brocher Foundation, Switzerland, September 2009.

implication: For a sustainable ethics of benefit sharing to become true it is not sufficient to develop a global medical science policy and research strategy that takes into account the particular research for health needs of poor and low-income countries. What is needed in addition is the development of national research policies in the richer part of the world that include sustainable plans for *how* the benefits resulting from these research programs can be shared in an equitable way with poor and low-income countries. How could poor and low-income countries then be involved in the *co-evolution* of a fair and sustainable global policy on scientific literacy and benefit-sharing? First tentative answer: By focusing the attention on ways of involving stakeholders from poor and low-income countries in the design, conduct and evaluation of national research programs in the affluent part of the world, i.e.:

- academic stakeholders
- members of National Bioethics Committees
- policymakers

Second tentative answer: By giving priority to national research programs that aim at forms of benefit *directly* transferable to poor and low-income countries. Third tentative answer: By giving priority to national research programs that aim at investigating the role and risks of respect for cultural diversity and pluralism in the design, conduct and evaluation of national research programs.

Concluding remarks

An underlying argument throughout this presentation has been that there is a need for some sort of instrument or forum to bring evidence to the global community about the gross inequity in the world with respect to who's diseases are favoured in ongoing or planned research programmes. Such a forum should be empovered to act as a global watchtower aimed at uncovering the economic, cultural, political and structural deficiencies hampering benefit sharing and generating inequities in the world with respect to health related research and development. In addition, such a forum should be empovered to serve as an instrument to monitor on-going research in poor and low-income countries to safeguard their rights to enjoy the benefits generated from this research. For such a forum to be able to function in a pro-active way close collaboration with national bioethics committees and health authorities as well as with international bodies such as the Council of Europe, UNESCO and WHO and would be important. Finally, such a forum should be empowered to hold countries unwilling to implement a fair and sustainable policy of benefit sharing accountable for lending support to gross human rights violations in the name of medical and health-related research.

In the WHO report on Macroeconomics and Health two proposals are put forward that seem to prefigure the idea of creating such a forum.[122] For a first, the establishment of National Commissions on Macro-economics and Health in poor and low-income countries. For a second, the creation of a Global Health Research Fund (GHRF) to «...support basic and applied biomedical and health sciences research on the health problems affecting the world's poor and on the health systems and policies needed to address them». An endorsement of those proposals by the international political community and commitment on the part of those countries capable of contributing resources to such a research fund would be powerful signals to the world of medical and health-related research that human rights matter. The creation of a Global forum for benefit sharing in health related research could make this message come true.

[122] WHO, Report of the Commission on Macroeconomics and Health, Geneva 2001.

Session 4 – Equity of access
Ethical and societal perspectives

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Abstract

The convergence of nanotechnology, biology, information technology and the cognitive sciences strengthens old and well-known risks of discrimination and marginalization. Poverty and lack of advanced education prevent individuals and peoples from sharing the benefits of these advancements. The gap impinges not only upon everyone's ability to exercise effective freedom of choice on the most relevant matters affecting our daily life, but also on the way we look at our "physical" as well as "societal" body. This is the dark side – in terms of equity, equality and justice – of unprecedented opportunities to make our lives better and the first and main reason to address at the *global* level the ethical responsibilities that stem therefrom. At the same time, emerging technologies produce emerging issues. Not coincidentally, the Report of the International Bioethics Committee of UNESCO on the Principle of non-discrimination and non-stigmatization, finalized in 2014, focuses on biobanks, nanotechnology and neurosciences as possible drivers of new risks. Suffice it to mention the effect of reshaping the fundamental concepts of normalcy, disability, health and disease, or the possibility that powerful governments and corporations make use of more and more intrusive (and often invisible) methods of gathering data to erode the principles of privacy and confidentiality, with the aim of controlling populations or for market-oriented strategies. Such a "panopticism" endangers civil liberties and opens the door to insidious forms of exploitation. Converging technologies require converging awareness and debate. Promoting scientific education is obviously key, together with a strong effort to build forums to disseminate transparent information and give all the relevant stakeholders their say.

Emerging technologies are a powerful means to promote development for all peoples and human beings. However, they entail at the same time the risk of deepening inequalities and creating new forms of discrimination and marginalization. In this perspective, three issues are key: accessibility as affordability; scientific education to boost awareness and autonomy; sharing as actual participation. The figures provide evidence of the differences existing among countries, but also within them.

Safety and *acceptability* are usually the keywords when emerging technologies are put under scrutiny. The former is an issue for scientists, who are called on to thoroughly assess their impact both on the environment and human beings. The latter is an issue for ethicists and eventually for all citizens, who

are confronted with unprecedented developments, which were simply unforeseeable until few years ago and are likely to deeply reshape our everyday life. The trend of “technology becoming biology” and “biology becoming technology” epitomizes a complex and multifaceted array of phenomena, stretching between the cornucopia of overflowing promises and the Pandora’s jar of the direst nightmares, while the blurring boundaries between medical and nonmedical use opens for the powerful actors of globalized market new opportunities to draw on.

It goes without saying, that these perspectives, concerns and responsibilities are and will remain the preliminary issues to address, building on the one side on sound scientific evidence and, on the other side, on the framework of universal human rights. In order to underscore the relevance of the possible outcomes, suffice it to quote the chapter on nanotechnology in the *Report on the Principle of Non-discrimination and Non-stigmatization* finalized in 2014 by the UNESCO’s International Bioethics Committee:

> Nanotechnology can provide low- and middle-income countries (LMICs) with clean, affordable, and reliable ways to harness renewable resources, averting recurrent energy crises, dependence on fossil fuels, and environmental degradation brought about by the depletion of oil and coal. It also promises solutions for energy generation and storage, water treatment, and air pollution remediation. Advances in nanotechnology can be used to create inexpensive, easily transportable, and easily cleanable water treatment. Nanoapplications and nanodevices can be developed for cheap, easy to use, highly sensitive and specific, robust, portable, handheld point-of-care diagnostic kits. Nanoparticle systems have also been created for use in medical imaging. Nanodevices based on nanotubes and nanoparticles have been designed to monitor in situ the concentrations of physiological variables such as glucose, carbon dioxide, and cholesterol. Novel delivery systems for the slow and targeted release of drugs and vaccines, with desirable features such as thermostability, single dose application, and needle-free use, can help increase shelf life and reduce both required dosages and transportation costs. Inexpensive agricultural applications of nanotechnology such as nanomaterials designed for the slow release and efficient dosage of fertilizers for plants and of nutrients and drugs for livestock can help decrease malnutrition, and thus childhood mortality, by increasing soil fertility and crop productivity, especially in rural regions of the developing world (p. 24).

Not coincidentally, this acknowledgment of the huge potential of emerging technologies for progress and social development is part of a reflection on the new risks of discrimination, marginalization and stigmatization entailed in these advancements, as a consequence of the high level of human and material resources required. As long as education and wealth remain a source of inequality, the most spectacular achievements that these technologies make possible are likely to deepen these gaps rather than reduce them. This is where the issue of *access* steps in. Emerging and converging technologies are unquestionably a powerful means to improve the project of making human life better, if not perfect. At the same time, they pledge to introduce a new paradigm in health care, as it is the case with the so called precision or personalized medicine: they have direct impact on one of the fundamental rights of every human being. As soon as they pass the safety and acceptability tests, the question therefore arises whether and how these benefits will be shared «with society as a whole and within the international community, in particular with developing countries», to quote Article 15 of the *Universal Declaration on Bioethics and Human Rights* of 2005. Unequal access to them – so the Report of the IBC goes on – would deepen the gap «both among countries and among communities, exacerbating the already marked resource and power disparities between the rich and the poor, and further increasing the vulnerability of a large majority of the human population to poverty, disease, inequities, and exploitation» (p. 24).

So, this is the challenge. The principle of sharing of benefits, as enshrined in Article 15 of the *Universal Declaration* of 2005, entails the idea of access both to quality health care and to scientific and technological knowledge. At the same time, it explicitly points out that «capacity-building facilities for research purposes» are to be considered an essential component of the commitment to sharing, which is not to be confused with a more or less continual flow either of top-down beneficence or of trickling-down effects. Building on this perspective, and taking into account that emerging technologies are having an impact on the broad range of major determinants of human life quality, which are in

most cases determinants of health as well, three priorities need addressing, in order to ensure *equity* of access:

1) Accessibility as affordability
2) Scientific education to boost awareness and autonomy
3) Sharing as participation

Accessibility as affordability

Surfing on the internet, it is easy to find out examples of applications of scientific knowledge which are becoming not only accessible, but more and more affordable. The most illustrative one is probably offered by direct-to-consumer genetic tests. Genetic analyses have become quite cheap and comprehensive: people may address a service provider by themselves to satisfy not only the wish to know about their possible predisposition to some diseases, but also the most various curiosities related to lifestyles or supposed abilities. In this case, the most urgent issue to address appears to be that of *informed* access, together with the necessity to stem the flow "over the borders" of false promises and help people limit unnecessary over-use of over-commercialized test opportunities as well as manage the results, which may easily become a source of overemphasized worries and anxiety.

However, it remains true that the cost of new and in many cases helpful and life changing technologies remains high and ensuring equitable access to them may be difficult even within rich countries, not to mention the duty to share such benefits with the international community and in particular with developing countries. The cost of a prosthetic limb or hand, to provide just an example, can reach up to tens of thousands of euros or dollars. We know that promising research projects are focusing on the possibility to produce lightweight, myoelectric prosthetic limbs and some prototypes have already been realized, with the aim of restoring even sensory perception and doing it relatively low-cost. Of course, all these advancements deserve financial and societal support, which may yet not be enough. For instance, what about the war amputees throughout the world, for which a "low" cost for the citizen of a rich country, who is also assisted in many cases by a public health service, will be always too much? Two viable strategies are worth considering.

The first one makes use of scientific progress itself. Keeping the example of prosthetic hands and limbs, the further development of technology is likely to dramatically cut down the costs, as it has always happened with breakthrough innovations. The second strategy builds on a consolidated experience and debate. Return on investment is essential, at least in the case of private investment, in order to make resources available for further research and progress. The intellectual property regime has a valuable function, which has yet to be balanced with other principles and fundamental human rights. This is what the international community has already acknowledged. The Doha *Declaration on the TRIPS agreement and public health* of 2001 pointed out that «each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency». The *Venice Statement on the right to enjoy the benefits of scientific progress and its applications*, which was the outcome of a meeting held in 2009 and organized jointly by UNESCO and the European Inter-University Centre for Human Rights and Democratisation, in cooperation with other international institutions, affirmed unequivocally that we have «a common responsibility to prevent the unacceptable prioritization of profit for some over benefit for all» and that States and governments are therefore called on, among others, «to promote access to the benefits of science and its applications on a non-discriminatory basis including measures necessary to address the needs of disadvantaged and marginalized groups». First and foremost, when life itself is at stake.

The benefits of science, which are relevant for the fundamental needs of human beings, broaden their scope when biology and technology *converge*. This is why the issue of access itself ought to be addressed nowadays in a broader and more encompassing perspective. Therefore, a first proposal should be considered. The existing international instruments on biomedicine, including the Oviedo Convention, ought to be updated and extended, according to the observation that the distinction between what is within the medical domain and what is outside it is blurring. The idea of «equitable

access» (Art. 3 of the Oviedo Convention) needs reshaping, in order to include those converging technologies which are likely to produce a great impact on the quality and the protection of human life and health. It is important not only to highlight the new obligations to meet, but also to explain *how* to perform the task, taking into due consideration the several aspects involved. Especially at the international and global level, where it is more difficult to introduce and implement legally binding instruments and make human rights justiciable, widespread agreement on and support to several and complementary forms of *soft law* may be a first yet essential step to boost equity of access. The question is open, whether to perform the task by modifying existing documents or proposing new ones.

Scientific education to boost awareness and autonomy

The Rathenau Instituut Report *From Bio to NBIC convergence* and the University of Bergen Report on *Ethical Issues Raised by Emerging Sciences and Technologies*, which were proposed as a basis for reflection to the participants in the CoE Conference on *Emerging Technologies and Human Rights* (Strasbourg, 4-5 May 2015), focus on two aspects which suggest immediately the issue of education. The first one underscores the possible consequences of the more and more dominating tendency to consider autonomy and self-determination not only as the cornerstone of the new paradigm of medicine, but also as a powerful driver of a new market-oriented normative framework, which is reshaping political institutions, practices and communication:

> From a political perspective, we see a move in many countries from government regulated to more market-driven forms of health care. This market approach addresses individuals more and more as consumers of health care, emphasizing the need for individual empowerment, individual responsibility for a healthy lifestyle, and the ability to choose. The increased use of biomedical technologies in the public domain is also promoted from the bottom up by several groups within society [...] This lowers the threshold for people to diagnose and intervene in their own bodies, an activity which, for a long time, has been strictly bounded to the highly professionalized medical domain [...] Without new forms of governance, the dynamics of these developments will be left to a variety of techno-scientific drivers and market forces. Obviously, there is a need to deal with the multifaceted ethical and regulatory challenges that are arising from these developments. This need implies an inclusive process of *societal learning* (p. 38 and 41).

This need for inclusion through learning and therefore education, which is also the bulwark of real autonomy and prevents the individual from becoming the unaware recipient of hetero-directed trends and consuming choices, is implicitly underpinned in the Bergen Report through the reference to the importance of fostering greater and more widespread knowledge as well as aware prudence in front of the unprecedented uncertainty and complexity which characterize the development of converging technologies:

> There are two reasons why uncertainty and complexity are particularly important with regard to nanotechnologies. First, there is scientific reason to expect surprising side-effects of nanostructures that cannot be predicted and controlled in advance. It remains to see the extent to which they can be detected early or if we will encounter new “late lessons” similar to asbestos, DDT and thalidomide. Secondly, the scientific belief in control is a leitmotif in the dominant sociotechnical imaginaries of nanotechnology. The nano-scientific community actively creates and introduces uncertainty into the world but is by its own thought-style less prone to understand it (p. 5).

Sociotechnical imaginaries – as the Report correctly points out – «have real influence on research practice and policy» and their production «has been dominated by scientists, innovators and investors» (p. 13-14). It is time to take seriously the commitment to promote an effective, informed and fair engagement of the public opinion in making decisions on what cannot be considered relevant only with regard to individuals and their own life, because effects and consequences rebound on the whole society. Needless to say, it is essential not only to give all stakeholders their say, but also to provide the solid ground of transparency, information and trust, without which *democratic* debate is always on

the verge of turning itself into a democratic illusion. In order to do that, some priorities have to be set, together with a consistent strategy to address them.

Promoting scientific knowledge is quite obviously a task to perform, with the clarification that the goal to achieve is not necessarily that of graduating more engineers or physicists. The knowledge we are talking about is the means to foster appropriate awareness among the whole population of the impact, opportunities and possible risks entailed in emerging (as well as "old") technologies, considering that this need is more urgent when what we should be aware of may well be pervasive, invisible and sometimes even deceptive. It is less obvious and much more difficult to focus on the many several sources of differences among and within countries and take the commitment to significantly reduce them as soon as possible.

The well-known Programme for International Student Assessment (PISA), which is a triennial international survey which aims to evaluate education systems worldwide, tested in 2012 around 510.000 students in 65 countries, representing about 28 million 15-year-olds. The mean score in Science, which was assessed together with reading and mathematics, suggests, among others, two observations. The first one is that differences among countries, at least when looking at the mean score, do not simply overlap with the figures of GDP. We find at the top of the ranking countries like Japan (547), Finland (545), South Korea (538). The United States (497) comes much lower and a country like Qatar falls even below the threshold of 400 points. Of course, no one could seriously say that the United States is lacking opportunities of access to the highest standards of education. What we have to say is that, according to the approach introduced also in the Human Development Index, we should get used to work out an inequality-adjusted index for education, as we have been doing long since for personal income.

The second observation concerns exactly the reasons of differences *within* countries. An effective policy to address them requires an appropriate awareness of their complex and interconnected variety. It is no surprise to establish that wealth makes a difference (even though, as we have seen right now, its impact deserves a deeper and more nuanced insight) as well as factors like gender and others. The United States, notwithstanding the progresses and the many efforts that have been done, is still characterized by noticeable differences related to ethnicity and race. Considering the number of graduate students in science and engineering in doctorate-granting institutions in 2013, the percentage of Black or African American not Hispanic or Latino, who were US citizens or permanent, was 6,23%, while the same percentage on the general population was 12,85% (even though, also in this case, there is no quick fix interpretation: the corresponding figures as to Asian students were respectively 8,93% and 5,21%). A country like Italy provides a striking example of how relevant *regional* distances may be. The score of Lombardy (529) is higher than the mean score of Germany (524), United Kingdom (514) and France (499). Calabria (431) is ranked together with Costa Rica (429) and Thailand (425). Only Montenegro (410) and Albania (397), among the European countries, come lower.

PISA is being criticized for many reasons and it goes without saying that its results do not allow any generalization: especially in those countries, where an adequate threshold of wealth has been reached, people and institutions are not inevitably prevented from attaining high standards of education, just because of a more disadvantaged context. First and foremost, these figures should never be used to offer opportunities to individuals dependant on where they come from and considering it as a predictive indicator of their qualities, competences, and abilities. However, they urge States, governments, and the international community to focus on the many possible sources of significant differences in terms of dissemination of knowledge and access to it both among and within countries.

These differences create conditions of potential privilege or vulnerability also with regard to emerging and converging technologies. This is why education is key, in order to boost awareness of the new opportunities offered through the advancements of science as well as the related ethical challenges. A second proposal is therefore to adopt a medium and long-term strategy, which should bind all relevant actors, also through the existing national and intergovernmental committees:

a) to monitor the gaps with regard to scientific knowledge both among and within countries as well as the concrete outcomes of the solutions to address them;
b) to promote "open" access to scientific knowledge;

c) to offer specific fora and other opportunities to focus on the new advancements and help the media disseminate sound and reliable information.
The opportunity to introduce the study of bioethics in the secondary education should also be considered.

Sharing as participation

Technological developments – to quote again the Bergen Report – can deepen global divides, because they «create or change infrastructures that exclude those who do not possess access or knowledge to use the technology» (p. 36). Therefore, participation, underpinned by education, entails first and foremost the ability «to play a proactive part in the democratization of the production of sociotechnical imaginaries and thereby our common scientific and technological future, for instance by developing and encouraging participatory foresight exercises, upstream engagement and other practices of what has been called "responsible research and innovation"» (p. 7). For the same reason, participation is also about the political decision-making procedure, which sets legal regulations and allocates resources. There are growing worries about the possible *Panopticon* effect of technologies that may enable governments or big corporations, but also employers and insurance companies, to intrude into people's life, gather data, influence and eventually control their personal choices, celebrating autonomy at the same time that it is eroded or even turned into an empty word.

Of course, this is all true and requires both whistleblowers and appropriate measures to protect citizens' freedom and privacy. However, the link between participation and access entails another meaning and responsibility, which can be illustrated through the figures concerning patents. Let's take the example exactly of micro-structural and nano-technology. According to the WIPO Statistics Database, patents publications by filing office for the period 2010-2013 show a dramatic cliff rather than a simple divide. High-income countries contribute to the total with 8.633 patents and other 4.665 patents refer to upper middle-income countries. The contribution of lower middle-income and low-income countries is less than minimal: 12 and 2 patents publications respectively. The figures concerning the applicant's origin confirm the picture, even though signalling at the same time that new powers and superpowers have rapidly climbed the ranking: China 2916; USA 2191; Republic of Korea 2147; Japan 1615; Germany 1181; Russian Federation 731; France 575; United Kingdom 138.

By underlining the importance of capacity-building as the other and complementary side of the coin with respect to access to scientific knowledge, the *Universal Declaration on Bioethics and Human Rights* of 2005 anticipated a priority, whose importance has been reinforced exactly by the pace of the advancement of new technologies, which builds on huge investments and the availability of a high level of human capital. The low-income countries could not have the ability to catch up with such development and the distance is due to grow, unless appropriate policies are implemented. Knowledge will be produced in few countries and then transferred to the others, according to some principles of justice, equity and fairness. The poor will always come later.

Turning "brain drain" into real "brain circulation" is certainly key, as long as we understand it as the epitome of a broader commitment to reduce the gaps. The WHO, in its World Health Report of 2006, which had the significant title "working together for health", summarized in a very effective way the many reasons of the one-way flow of these skilled workers:

> Migration takes place within countries from rural to urban areas; within regions from poorer to better-off countries and across continents. A better life and livelihood are at the root of decisions to migrate […] Workers' concerns about lack of promotion prospects, poor management, heavy workload, lack of facilities, a declining health service, inadequate living conditions and high levels of violence and crime are among the push factors for migration. Prospects for better remuneration, upgrading qualifications, gaining experience, a safer environment and family-related matters are among the pull factors (p. 99).

Emerging technologies are a powerful driver, which could exacerbate this trend, rather than reverse it. A broad-ranging array of interventions and a deep change in the mindset itself of cooperation are required, including networking of people and institutions, fundraising, circulation and dissemination of information. This is the third proposal to boost equitable access to the benefits of scientific progress. A significant share of research and cooperation funds should be allocated to this goal, encouraging bi-

and multilateral projects. Empowerment is key. The «hubs» of emerging technologies are concentrated in few countries. Given this condition, access is likely to remain a matter of beneficence more than active participation. The real and effective way out of this trap of inequality can only be transforming as many developing countries as possible in *producers* of knowledge and not only *beneficiaries* of a top-down flow of benefits. The recent history of some countries, which are now big players of research and technology, provides evidence that this is a difficult, but not an impossible task to perform.

Conclusions

Against the background of the new ethical and societal challenges stemming from the development of emerging technologies, States, governments, the community of scientists as well as all citizens are called on to adopt and implement an articulated strategy of inclusion, protection and promotion of awareness and autonomy, and participation. Three recommendations have been proposed:

1) to extend the principle of “equitable access” enshrined in many international instruments, in order to include those converging technologies, which are likely to produce a major impact on the quality of life and the protection of health;
2) to adopt a strategy for education aiming at reducing the gaps with regard to scientific knowledge among and within countries, promoting “open” access to it and offering specific fora and opportunities to disseminate sound and reliable information;
3) to make brain and knowledge circulation a priority, through new frameworks of cooperation and fundraising, networking of people and institutions, and other initiatives oriented to enable as many countries as possible to become producers and not only beneficiaries of emerging technologies.

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Session 4 – Equity of access
Human rights challenges

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Abstract

Access and benefit sharing

Access and benefit sharing is one of the greatest problems currently faced in the biomedical field. The principles of dignity, justice and equality must be compatible with the rights of all the agents involved in biomedicine, often with scarce resources. In the necessary weighting of rights, property and legitimate interests, it is of utmost importance that none of the essential principles, as reflected in relevant international standards, are harmed.

On the one hand, regarding equitable access to health care, Article 3 of the Oviedo Convention establishes that "*Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality*". On the other hand, the Universal Declaration on Bioethics and Human Rights (UNESCO, 2004) also addresses this important problem in Article 4 (*Benefit and harm*) and, in particular, in Article 15 (*Sharing of benefits*) which states that: "*Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries*" and lists some instruments for its implementation including: special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research; access to quality health care; provision of new diagnostic and therapeutic modalities or products stemming from research; support for health services.

The current international regulatory framework informs us how access and sharing of benefits should be interpreted to comply with and preserve the principles of dignity, justice and equality.

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1. Human rights and biomedical research: introduction

The development of biotechnology and biomedical research presents challenges that must be studied and that require adopting specific measures to guarantee the rights of the persons involved in the scientific research processes. As is well known, the aim of the Convention on Human Rights and Biomedicine (CHRB), as defined in Article 1, is to protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine. This definition obviously includes biomedical research.

Both at a level of the States, as well as in the international and supranational arena, research is recognized as a fundamental right that allows achieving considerable progress for humanity. Progress in medical and biological sciences, in particular, the advances achieved through biomedical research, contributes to saving lives and improving the quality of life. In addition, in many cases, the participation of healthy volunteers and patients in biomedical research is absolutely necessary and has been acknowledged in the Convention on Human Rights and Biomedicine and the Additional Protocol Biomedical Research. In relation to this, Article 15 (Chapter V - Scientific research) of the Convention on Human Rights and Biomedicine establishes that "*Scientific research in the field of biology and medicine shall be carried out freely, subject to the provisions of this Convention and the other legal provisions ensuring the protection of human beings*", and Articles 16, 17 and 18 regulate this matter in detail[123]. Specifically, Article 16 details the protection of persons undergoing research who may only be undertaken if all the following conditions included in Article 16 are met[124]. The guarantees contained in Article 16 are consistent with the principle of primacy of human beings recognized in Article 2 of the Convention (*The interests and welfare of the human being shall prevail over the sole interest of society or science*).

On the other hand, the article 13 of the Charter of Fundamental Rights of the EU includes the scientific research like a fundamental right[125] which *shall be free of constraint.* As the Explanations relating to the Charter of Fundamental Rights of the European Union states, this right is deduced primarily from the right to freedom of thought and expression and may be subject to the limitations authorised by Article 10 of the European Convention on Human Rights[126]. Scientific research and, specifically, biomedical research there is not an unlimited rights and one of the most relevant limitation is the rights of the human being.

As a fundamental right, biomedical research correctly interpreted includes an axiological canon requiring that it be carried out in a manner consistent with respect for human dignity and fundamental rights, but also in accordance with the objective to fulfil its primary purpose: Achieve safe and responsible scientific progress whose results can be made available to society. Scientific research cannot be separated from the goal of maximizing benefits and minimizing risks and inconveniences for the patients or volunteers participating in the research.

Doubtlessly much has been achieved in the recognition and protection of persons in this field, but it is necessary to continue working. Not only the legislation (hard law), but also the documents of soft law and bioethical principles have played a considerable role in achieving certain levels of protection for human beings in biotechnological and biomedical research. However, further work is needed to ensure that the assurance of human dignity and fundamental rights is truly effective and equally applicable in as many countries as possible. Today, there are still some aspects of biomedical research that are poorly regulated, or many different regulations that do not sufficiently ensure freedom, dignity and equality of human beings in these areas. One of these areas that still require further study with ethical and legal regulation is the participation of healthy volunteers and patients in the benefits generated by the biotechnological and biomedical research.

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[123] Article 16 on *Protection of persons undergoing research*, Article 17 on *Protection of persons not able to consent to research*, and Article 18 on *Research on embryos in vitro.*

[124] Article 16: *Research on a person may only be undertaken if all the following conditions are met: there is no alternative of comparable effectiveness to research on humans; the risks which may be incurred by that person are not disproportionate to the potential benefits of the research; the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of the research, and multidisciplinary review of its ethical acceptability; the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection; the necessary consent as provided for under Article 5 has been given expressly, specifically and is documented. Such consent may be freely withdrawn at any time.*

[125] Article 13 Charter of Fundamental Rights of the European Union*: Freedom of the arts and sciences. The arts and scientific research shall be free of constraint. Academic freedom shall be respected.*

[126] Article 10.2 European Convention on Human Rights states: 2. *The exercise of these freedoms, since it carries with it duties and responsibilities, may be subject to such formalities, conditions, restrictions or penalties as are prescribed by law and are necessary in a democratic society, in the interests of national security, territorial integrity or public safety, for the prevention of disorder or crime, for the protection of health or morals, for the protection of the reputation or rights of others, for preventing the disclosure of information received in confidence, or for maintaining the authority and impartiality of the judiciary.*

As we know, the recognition of the right to participate in the benefits in the field of medical treatment, research, or in the use of natural resources[127] is mentioned in important international documents and in the national legislation of some countries. However, of these three areas (health care, research and natural resources), research is the area where less uniformity has been obtained in the recognition of the rights of the healthy volunteers and patients who are involved in these processes. For this reason, we should insist on the need to implement the acknowledged principles and also reflect on the necessity of introducing other measures to enforce access and participation of healthy volunteers and patients to the benefits generated by biotechnological and biomedical research.

We are aware that this is a very delicate issue since participation in the benefits derived from biomedical research could have undue influences, or create other forms of pressure on the persons involved, which could affect their freedom of choice. These risks must be avoided by introducing rules and principles to guarantee the full autonomy of the participants. Moreover, we should not forget that healthy volunteers and patients contribute decisively to the results of scientific research so that it is ethically correct that they should receive some type of compensation, while participating, individually or collectively, in certain benefits derived from the research. In research involving human subjects, distributive justice requires the equitable distribution of both the burdens and the benefits of participation in research[128].

It is very important to point out that the concept of profit defended here is not limited to the subject receiving financial amounts – although they may be included - but *benefits* should be understood to be any incentive, whether financial, in kind or moral, which the subject may receive for participating in this type of scientific processes and any reward or compensation, equally financial, in kind or moral for related third parties or institutions, mainly non-profit organisations that may be designated by the subject as beneficiaries of the results of the scientific research.

The problem is how and in what way this participation in the benefits of biomedical research can be regulated without infringing the general principle of non-commercialisation of human beings and without creating undue influence on the participant. My reflections on this issue are given below.

2. Participation of healthy volunteers and patients in biomedical research

Surely there is no need to recall that biomedical research requires the collaboration of healthy volunteers and patients during the various stages of their processes. This is especially important in the case of clinical trials using medicines, but not only here. As long as there are no reasonable and scientifically feasible alternatives to replace the participation of volunteers in biomedical research, it does not seem appropriate to make exclusionary ethical and legal judgements that would only shift the debate away from reality. Therefore, as long as participation of volunteers is unavoidable, the ethical and legal debate must be based on this fact while weighing up the rights and interests involved in these processes.

On the one hand, the participation of volunteers requires the implementation of a specific bioethical and legal protocol that must take their interests, objectives, and protection of their rights into account. In this respect, the key international documents have highlighted the obligation to respect human dignity and to ensure the welfare and protection of the rights of individuals in the field of biomedicine, and have also highlighted the principle of primacy of the interest of human beings before the interest of society or science. Some good examples are Articles 2, 3[129], 16, and 17 of the Convention on Human Rights and Biomedicine; Articles 1 and 3 of the Additional Protocol Biomedical Research; Articles 1 and 3 of the Charter of Fundamental Rights of the EU; Articles 3 of the Regulation (EU) No. 536/2014 on the EP /C of 16 April 2014 on Clinical trials on medicinal products for human use; and Articles 1, 3, 6, and 12 and Articles 2 c), e) and f) of the Universal Declaration on Bioethics and Human Rights – UNESCO.

[127] As we know, the recognition of the right to participate in the benefits in the field of medical treatment, research, or in the use of natural resources is mentioned in important international documents and in the national legislation of some countries. *Regulating Access and Benefit Sharing: Basic issues, legal instruments, policy proposals,* Bonn, October 2001.

[128] *International Ethical Guidelines for Biomedical Research Involving Human Subjects*. Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO). Geneva, 2002. Available at: http://www.cioms.ch/publications/guidelines/pautas_eticas_internacionales.htm

[129] Article 3 which states: *Primacy of Human Beings. The interests and welfare of human beings participating in research shall prevail over the sole interest of society or science.*

On the other hand, the main objective of biomedical research is to improve the lives of individuals and society, but it is potentially capable of generating other equally legitimate benefits including commercial and financial gains[130].

Relevant international documents have indicated the importance that the results and benefits derived from the research are shared with those who helped to generate them and finally with the society at large. In this regard, the cited Article 15 of the Universal Declaration on Bioethics and Human Rights, UNESCO, which clearly states the obligation to return part of the benefits obtained from the research to the society, is highly significant[131].

Article 15.1 of the Universal Declaration (Benefit Sharing) addresses the general principle that benefits resulting from any scientific research and their applications should be shared with society as a whole and within the international community, in particular with developing countries but paragraph 2 states that benefits should not constitute improper inducements to participate in research.

As we know, the principle of prohibition of financial gain is included in relevant international conventions and other documents like the Article 21 of the Convention on Human Rights and Biomedicine which states "The human body and its parts shall not, as such, give rise to financial gain". Likewise, Article 3.1 c) of the Charter of Fundamental Rights of the European Union[132]. However, a distinction should be made between the concepts of "financial gain" and "participation in the benefits derived from the research". The first implies a commercial marketing of the relationship between participants and researchers, which I do not agree with. The second, however, is a concept that allows the results and even a small part of the benefits derived from the research to flow back to society and to the participants themselves. In this respect, the Explanatory Report of the Oviedo Convention (paragraph) 132) specifies however, that "technical acts (sampling, testing, storage…) which are performed on the basis of these items may legitimately give rise to reasonable remuneration". Furthermore, "[Article 21] does not prevent a person from whom an organ or tissue has been taken from receiving compensation which, while not constituting remuneration, compensates that person equitably for expenses incurred or loss of income (for example as a result of hospitalisation)"[133].

At present, in several European countries, the healthy volunteers involved in biomedical research may receive some type of compensation or remuneration but the situation regarding patients is more restrictive. Finally, the current rules are not uniform and are unequally applied, which can generate injustice and insecurity in some cases. In my opinion, it would be necessary to reflect on these problems and obtain a consensus on the basic criteria to regulate the participation of healthy volunteers and patients, in the benefits derived from the research to achieve at least a European standard on this issue.

At this point, it is important to distinguish the area of biomedical research for the donation of organs, tissues and biological materials for therapeutic purposes only. Some principles such as human dignity, justice, equality of treatment must be rigorously applied both in therapeutic fields and biomedical

[130] In this comment I refer exclusively to benefit sharing in relation to biomedical research. The issue of regulated organ donation is not discussed here. On this matter some references could be: *Directive 2010/45/EU of 13 July 2010 amending Directive 2006/112/EC on the common system of value added tax as regards the rules on invoicing*; Horizon scanning meeting on the prohibition of financial gain (DH-BIO, 16 December 2014 in Paris); Statement on the prohibition of any form of commercialisation of human organs (DH-BIO).

[131] Article 15 – Benefit-sharing*. 1. Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. This principle, benefits may take any of the following forms: (a) special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research; (b) access to quality health care; (c) provision of new diagnostic and therapeutic modalities or products stemming from research; (d) support for health services; (e) access to scientific and technological knowledge; (f) capacity-building facilities for research purposes; g) other forms of benefit consistent with the principles set out in this Declaration.*

[132] Others relevant references: Directive 2002/98/EC of 27 January 2003, setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC which states that Member States "take the necessary measures to encourage voluntary and unpaid blood donation…"; Directive 2004/23/EC of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells which states: "Member States shall endeavour to ensure voluntary and unpaid donations of tissues and cells" and the donor "may receive compensation provided that it is strictly limited to making good the expenses related to the donation".

[133] Committee on Bioethics (DH-BIO); Horizon scanning meeting on the prohibition of financial gain, 16 December 2014, Paris; Summary of the main points highlighted during the meeting, p. 2.

research, but not others like benefit sharing. In addition, sometimes research and therapeutic applications are linked.

The differences between organs and tissues donated for patient treatment purposes and for biomedical research were highlighted during the discussion on Horizon scanning meeting on the prohibition of financial gain which states: Does one type of donation have more value than the other, and would an incentive be more ethically acceptable in one case than the other? [134]

In my opinion, it is necessary to distinguish these areas: research and therapeutic applications when referring to access and benefit-sharing. There are differences in the regulation of both fields that must be taken into account such as the fact that biomedical research generates, or may generate, benefits of a different nature (promotion of health and research, social welfare, economic benefits, etc.) and for different collective groups (researchers, developers, companies and industries). The healthy volunteers and patients, who participate in the research, should not be excluded from these benefits. This is the main idea.

How and with which guarantees the volunteers would access and participate in the benefits of the research is the most difficult and important question.

The first major problem encountered on studying this issue is a lack of clear and uniform legal definitions. In order to adequately address this problem it would be necessary to clearly define and apply uniform concepts such as: compensation; retribution; incentives; financial gain; non payment (unpaid); gratuity; donation (e.g. donations are compatible with payment of specific costs); "financial gain" is not a synonym for "non payment"; "incentive" is not a synonym for "retribution" and both can be in the form of money, but also in medical or social services.

It is well-known that in many cases some participants, mostly healthy volunteers, receive some type of compensation or remuneration, while the patients often do not receive the same treatment. These differences are based on the circumstances and conditions of the research itself and do not always take into account the rights and interests of the healthy volunteers and patients.

Researchers, promoters, industries are obliged to return part of the benefits obtained by the research to the participants and society. In my opinion, this obligation is based on the principles of "social responsibility" and "fair share and prohibition of unjust enrichment".

There is a bioethical and legal framework allowing to explore new ways of making the right of participation in the benefits of biomedical research (direct and indirect benefits) more effective, although, as already pointed out, the various documents are not homogeneously drafted and do not allow a common interpretation. For example, Article 15 CHRB; Article 6 and 12 Protocol Biomedical Research; Article 13 Charter of Fundamental Rights of the EU; Preamble, Article 2 d), 4, 6, 15, 19 and 21 of the Universal Declaration on Bioethics and Human Rights; Article 5.8 of the Code of Good Practice in the EU, etc.

To properly address this problem, the first issue that must be addressed is the prohibition of profit established in Article 21 of the CHRB[135]. The same principles can be found in Article 3 of the Charter of Fundamental Rights of the European Union, in Article 4 of the UDBHR-UNESCO[136], or in the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation.

The concept of prohibition of profits with the human body or parts of the same regulated in Article 21 of the CHRB is not synonymous with "free", nor is it directly incompatible with the right of access and participation in benefits, which is clearly recognized in other precepts, for example, in Article 12 of the Protocol on Biomedical Research. This article refers to the necessity of checking the funding of participants to avoid any "undue influence".

Chapter III, Article 9 of the Protocol of Biomedical Research establishes that "*Every research project shall be submitted for independent examination of its ethical acceptability to an ethics committee*" and

[134] *Idem*, p. 4.
[135] *Article 21* –Prohibition of financial gain- states: *The human body and its parts shall not, as such, give rise to financial gain".*
[136] Article 4 – *Benefit and harm.*

the Appendix on Information to be given to the Ethics Committee states: “xvi. Details of all payments and rewards to be made in the context of the research project”.

These examples allow us to claim that the access and participation of healthy volunteers and patients in the benefits of biomedical research in which they participate should be accepted in the resolutions of the Council of Europe and is supported by the principles of dignity, justice and equity, but that it would be necessary to develop a clearer, more precise and safer regulation for the participants, researchers and promoters.

A second and more important question is what criteria should this regulation on access and benefit-sharing have. At least, the following aspects should be taken into account in any future regulation:

a) The circumstances of the subject should be addressed. In this case, we should distinguish between healthy volunteers and patients, which could be adults, minors or persons without the capacity to consent. The personal circumstances of each participant should be taken into account.
   It is crucial to adequately assess the participation of persons without sufficient capacity to consent, or minors and, in the latter case, a distinction between minors in the strict sense and mature minors must be made. With regard to the participation of persons without sufficient capacity to consent and minors, the principle of exclusion of these groups must be applied unless direct therapeutic benefits for them could be obtained from the research, or their participation is crucial in scientific terms and the research could be described as highly useful to society. In any event, extreme care must be taken when obtaining informed consent by representation and the subject must be heard whenever their capacity or age allows an opinion in this respect. Due to their particular vulnerability, these groups should have priority in the participation of the research benefits.

b) The type of intervention should be taken into consideration distinguishing the following:
   - The more or less invasive nature of the research
   - Inconveniences of the normal development of the life of the subject (frequency and duration of the intervention and recovery time.)
   - Specific or possible risks (implications for health, consequences or secondary effects.)

c) Whether and to what extent the research could have specific or potential therapeutic benefits should also be taken into account. In any case, any potential or specific therapeutic benefits do not exclude the possibility of obtaining other type of benefits. The disease itself should not be a reason to exclude patients who should receive at least the same benefits as healthy volunteers. Patients should receive the same benefits as healthy volunteers and should never be discriminated against because of their illness. We know that some patients may agree to participate in scientific research hoping to obtain a therapeutic benefit. Whether this is possible or not, patients should be able to participate in other benefits in the same proportion and form as healthy volunteers.

The so-called "therapeutic misconception" leads the subject to not differentiate properly between clinical practice and clinical research so that they tend to consider, for example, that the mere participation in a clinical trial will generate a direct therapeutic benefit - which is not always true - and consequently the risks of participation can be erroneously assessed. It is a legal and ethical obligation of researchers to ensure the autonomy of the volunteers being necessary to provide all the resources required to ensure that the information is understood by the subject in a clear and comprehensive manner so as to obtain consent based on an informed decision. Avoiding therapeutic misconceptions is a very important objective in relation to participation in the benefits derived from research, as it could vitiate the free will of participants.

3. Method and form of participation in benefits derived from research

Obviously, a consensus must be achieved on the basic criteria relating to the extent and type of potential benefits. The benefits must not necessarily have any "economic value", but could also be welfare-oriented for the subject in the case of patients; or for a group (for example, an association of

rare disease patients). In any case, there should be a broad consensus on effective measures to avoid "undue influence", especially in the more vulnerable groups.

The potential benefits have various natures and scopes and should be defined and applied in strict relation to the circumstances, both of the subject and of the research process.

A first distinction should be made between potential benefits derived from the direct participation of the subject in the research and the benefits derived from the results:

a) possible benefits for the subject derived from their direct participation in the research or clinical trials could include:
    - Therapies/aids for the subject throughout the duration of the participation
    - Economic
        - Remuneration
        - Contractual model
        - Percentage depending on volume of the project
        - Risks and degree of involvement
        - Salary level
        - Model of reimbursement for loss of income
        - ✓ Reimbursement of expenses (only expenses actually incurred shall be reimbursed).
    - In kind

b) Benefits derived from the results obtained from the research or clinical trials:
    - Economic
        - Contractual
        - Percentage
    - Therapies/aids (for the subject, for third parties related to the subject or for institutions designated by the subject and related to the pathology or scientific area focused on by the research process)
    - In kind

The different types of potential benefits are not mutually exclusive so that subjects could receive a therapeutic benefit and a remuneration or compensation for expenses as well. Remuneration in kind may be more appropriate for the participation of minors or disabled persons (e.g. welfare assistance or educational care, etc.).

On the other hand, the potential therapeutic benefits can be for both the subject and related third parties (e.g. a treatment for several members of the same family) or, even for an institution linked to the pathology or scientific area to be investigated or tested (e.g. a donation to a patient's association).

Benefits in "kind" have the same purpose as stated in the previous paragraph, since it may be more suitable to compensate the participation of minors or incapable persons so that they are directly rewarded, and not their parents, guardians or legal representatives.

The acknowledgement of potential benefits derived from the results of biomedical research is much less extensive: the problems encountered here and the potential impact in the field of biotechnological patents is well-known. However, it could be argued that the participation of healthy volunteers and patients in the benefits derived from the research is justified by the essentialness of its contribution to achieve those results. There is no justification whatsoever, neither ethical nor legal, to exclude such essential participants from the results of the process. The right to participate in the benefits resulting from the research is founded in the principle of social responsibility, direct and indirect use of the benefits, benefit sharing and a fair assessment of the participation of the healthy volunteers and patients.

The promoters or exploiters of the research results are ethically obliged with the subjects involved, whether they had already received these direct benefits for their participation, or not. The persons and institutions are bound by the principle of social responsibility, the principle of participation, and the distribution of the benefits derived from the research among the various social actors. Both these principles are recognized in important international documents such as the Declaration of Bioethics

and Human Rights-UNESCO. Finally, a fair assessment of the subjects' participation would ensure that they could participate in some manner in the benefits derived from the results of the scientific process.

Finally, it would also be necessary to establish some basic criteria on the best forms or systems of access and benefit sharing. In this respect, the following options are possible:

- **a)** Legal recognition by drafting a specific document, or perhaps a new protocol or Annexe;
- **b)** There should be a mention in the Informed Consent recommending that the documents of consent contain estimates on access and benefit sharing;
- **c)** In some cases, by means of a specific document naming as beneficiaries not only the subject, but also patient associations or groups, or funding of research grants, health promotion, etc.

4. Conclusions

All volunteers, both healthy volunteers and patients, must be permitted access and participation in the benefits of biomedical research in which they participated in accordance with their personal circumstances and their contribution to the research activities.

Patients should not be excluded from these potential benefits due to obtaining an actual or potential benefit derived from the research. The disease itself should not be a motive for exclusion from potential benefits. This would be a "double jeopardy": disease and exclusion from benefits.

Participants involved in the control group should be entitled to receive any personal, therapeutic, social or economic benefits derived from the research or clinical trials in which they participated.

Patients should be guaranteed the treatment derived from any research in which they participated, if proven effective.

Minors, or persons not able to consent, who may not provide their consent, should preferably receive benefits that favour them directly (therapies, aids, social and educational assistance). The potential benefits that parents, guardians or legal representatives could receive should be regulated with special care to avoid "undue influence".

A common criteria should be developed to ensure that the action of the Ethics Committees, or any other bodies that may be responsible for the approval of research or clinical trials, act uniformly, especially in the assessment of the possible participation of the volunteers in the benefits derived from the biomedical research.

Session 5 – Governance
Introductory presentation: Overview of existing governance systems and available tools

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Abstract

Emerging Technologies and the Governable Subject

Since the early 1970s, Western societies have dedicated substantial intellectual energy and material resources to creating a socially acceptable balance between the benefits of emerging technologies and their potential harms. Grouped under the all-purpose rubric of risk, new analytic techniques and institutional mechanisms focused on identifying and assessing the range of possible harms, assigning probabilities to them, and reducing their impact by the best practicable means. Introduced into policy discourse in the early 1980s, the concepts of risk assessment and risk management quickly became staples in the toolkits of government, along with a host of predictive technologies. Surprisingly, however, risk-oriented techniques and practices failed to provide the reassurance publics seemed to be seeking, as exemplified most dramatically in the widespread rejection of agricultural biotechnology, but also for example in fears and panics over vaccines, radioactive wastes, human cloning, and nanotechnologies. In this talk, I will argue that good governance of emerging technologies calls for a richer imagination of the politics of technology, beginning with a rethinking of the subject who is being governed. Such rethinking is all the more urgent when new bio and information technologies are in effect rewriting the very meaning of being human. Using historical examples, and comparing across countries, I will suggest that the success or failure of governance instruments crucially depends on rendering the subject as capable of understanding as well as reason, and ethical as well as epistemic sense-making.

Session 5 – Governance
Are existing governance systems challenged by emerging technologies and their convergence?

Prof. Herman Nys (Belgium)

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Abstract

The title of this session is: *'are existing governance systems challenged by emerging technologies and their convergence?'* If we understand 'existing governance systems' as including, among others, the international human rights law, the answer to this question is obvious: yes. International human rights law is constantly challenged by emerging technologies.[137] During this conference several speakers have already discussed many examples[138]. That emerging technologies are challenging the international human rights framework is not at all a surprise given the high importance we attach to the respect for human rights, that are in principle and leaving aside exceptions such as the right to life, no absolute rights; the opposite would be a surprise and be an even more worrying challenge. In my opinion the central question is: *Is there a need for a special framework to secure the human rights and ethical principles in light of NBIC developments?*

It is not uncommon that individuals or organizations are requesting the explicit approval of 'new' binding human rights in light of the challenges that new technologies are confronting us with. Recent examples are 'the right to be forgotten' (online or not)'[139], the 'right to abstain from or avoid enhancement'[140] or the right of citizens 'to participate in the governance framework of emerging technologies'.

A clear understanding of the shaping and the development and also the 'non-development' during the last three decades of the international and the regional human rights law framework that specifically relates to bioethics offers us useful insights on how to deal in a meaningful way with the human rights challenges posed by the emerging technologies.

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[137] See Press Unit European Court of Human Rights, *Factsheet-New Technologies*, March 2015.
[138] See many examples in R. Strand and M. Kaiser, *Report on ethical issues raised by emerging sciences and technologies,* University of Bergen, 23 January 2015, Chapter 3.
[139] See for a critical appraisal H. Nys, 'Towards a human right "to be forgotten online"', *European Journal of Health Law,* 2011, 469-475.
[140] R. Strand and M. Kaiser, *Report on ethical issues raised by emerging sciences and technologies,* University of Bergen, 23 January 2015, 18.

Is there a need for a special framework to secure the human rights and ethical principles in light of NBIC developments?

The limits of regulating new technologies in international human rights law[141]

The main sources of binding international law are treaties (covenants; conventions) on the one hand and customary law on the other. However, alternative forms of international law making are flourishing in areas where states have not yet had the time or the willingness to formulate a formal and binding instrument on a subject. These alternative forms of international law are often referred to as 'soft law'.

At the universal (global) level today there is **no single international treaty on human rights and bioethics;** there is not even a single international treaty on human rights **in general**. There is of course the **International Declaration on Human Rights** but this is not a treaty. However, there is a growing consensus that at least some parts of the Declaration constitute customary international law and are a source of binding international law. In 2001 the International Bioethics Committee (IBC) of UNESCO set up an ad hoc Working Group to discuss the possibility of drafting a Universal instrument on human rights and bioethics.[142] This Working Group considered it preferable, at least in the initial stage, to settle on a (non-binding) Declaration on bio-ethics and not an international treaty given that the aim of an international instrument on bioethics should be by its nature broad and should receive the broadest acceptance possible by public authorities, the scientific community and the general public. A few years later, in 2005, UNESCO adopted the **Universal Declaration on Bioethics and Human Rights**. This Declaration is not a source of international human rights law because it is not a treaty nor can it be considered as customary international law given the obvious lack of consistent and harmonic state practice with regard to many issues of bioethical relevance. The arguments given by the Working Group not to opt for a binding instrument are still valid today. This does not mean that the Universal Declaration on Bioethics and Human Rights is worthless. It certainly constitutes soft law and soft law is especially in the field of bioethics an attractive choice. First because the field of bioethics has only rather recently come to the attention of international law makers and secondly given the rapidly changing field of bioethics that requires a flexible regulatory approach.

Turning now to the regional level, we observe that the situation is very much comparable with the universal level: **there are no regional binding human rights law instruments regarding bioethics**. There is of course **one notable exception**: the European Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine (Convention on human rights and biomedicine or Oviedo Convention) which has already been mentioned often in the course of this conference. This Convention is 'the most comprehensive attempt to place bioethical matters on a formal human rights footing'.[143] It has moreover the potential to become a universal instrument. Apart from the Member States of the Council of Europe, the following states, which took part in its preparation, may sign and ratify it: Australia, Canada, the Holy See, Japan, Mexico and the United States of America (Article 33 Oviedo Convention). Moreover the Committee of Ministers of the Council of Europe may, after consultation of the Parties, invite any non-Member State of the Council of Europe to accede to this Convention (Article 34 Oviedo Convention). However, until now no such invitation has been directed to any non-Member State while none of the non-Member States which took part in its preparation have signed the Convention. It is even the case that there are still Member States of the Council of Europe that did not even sign the Convention: no less than one out of four (12 out of 47). Thirty five Member States signed the Convention and twenty nine of these have ratified the Convention. The most recent ratification (France) dates already from end 2011. It is difficult to assess the reasons for not signing the Convention and probably local (national) motives are in general decisive. Richard Ashcroft has made a very interesting speculation in this regard: 'To the extent that the Oviedo Convention's provisions relate to biomedical research, it is significant that most of the countries with major pharmaceutical and life sciences industries have not taken up the Oviedo Convention'.[144] This is the case for Austria, Belgium, Germany, Sweden and the UK. Whatever the reasons, the point that I want to make is that the halting implementation process of the Oviedo Convention indicates that the field of bioethics cannot easily be subjected to binding

[141] Based on H. Nys, 'International law', in H. ten Have (ed.), *Encyclopaedia of Global Ethics,* 2015 (accepted for publication, in press).
[142] International Bioethics Committee, *Report of the IBC on the Possibility of Elaborating a Universal Instrument on Bioethics,* Paris, 2003.
[143] R.E. Ashcroft, 'Could Human Rights Supersede Bioethics?', *Human Rights Law Review,* 2010, 656.
[144] R.E. Ashcroft, 'Could Human Rights Supersede Bioethics?', *Human Rights Law Review,* 2010, 658.

international human rights law. And thus we have to be very prudent in creating 'new' binding human rights law or 'establish a new convention for ethics of science and technology in general, beyond the bioethical domain in a strict sense'[145] or to add an Additional Protocol to the Oviedo Convention related to the NBIC technologies. One should not overlook indeed that we have already an (all) encompassing European Convention on Human Rights (1950) and should use its potential as much as possible (see my second argument). Moreover, the Council of Europe disposes of a legal instrument (the so called Recommendations of the Council of Ministers to the Member States) to create soft international law and already has used this instrument many times in the field of bioethics and new technologies.[146]

The European Court of Human Rights and new technologies

This was my first argument. For my second argument I turn to the rich jurisprudence of the European Court of Human Rights (ECrtHR or Court) in the field of new technologies. Without pretending completeness it appears that different articles of the European Convention on Human Rights and Fundamental Freedoms are very relevant in light of the human rights challenges that the emerging technologies are confronting us with.
For instance article 10 of this Convention that protects the right to freedom of expression, that states the following:

1. Everyone has the right to freedom of expression. This right shall include freedom to hold opinions and to receive and impart information and ideas without interference by public authority and regardless of frontiers. This Article shall not prevent States from requiring the licensing of broadcasting, television or cinema enterprises.
2. The exercise of these freedoms, since it carries with it duties and responsibilities, may be subject to such formalities, conditions, restrictions or penalties as are prescribed by law and are necessary in a democratic society, in the interests of national security, territorial integrity or public safety, for the prevention of disorder or crime, for the protection of health or morals, for the protection of the reputation or rights of others, for preventing the disclosure of information received in confidence, or for maintaining the authority and impartiality of the judiciary.

From this right a 'right to citizens' involvement' can be derived. Swiss Courts had prohibited a citizen from stating that food prepared in microwave ovens was a danger to health and that it led to changes in the blood of those consuming it that indicated a pathological disorder and presented a pattern that could be seen as the beginning of a carcinogenic process. According to the ECrtHR this prohibition violated article 10: 'the effect of the injunction was thus partly to censor the applicant's work and substantially to reduce his ability to put forward in public views which have their place in a public debate whose existence cannot be denied. It matters little that his opinion is a minority one and may appear to be devoid of merit since, in a sphere in which it is unlikely that any certainty exists, it would be particularly unreasonable to restrict freedom of expression only to general accepted ideas'.[147] The (then still existing) European Commission for Human Rights had concluded that 'freedom of expression is of special importance for free debate on matters of public importance for the community'.

On the other hand the ECrtHR remains reluctant to use Article 10 as the basis for a general right of access to information. Since Article 10 expressly imposes on the State a negative duty not to interfere with the freedom to receive and impart information, the Court has been reluctant to recognize that this provision guarantees a general right of access to information, including administrative data and documents.[148] The Court has consistently held that the freedom to receive information prohibits a Government from restricting a person from receiving information that others wish or may be willing to impart on him and that this freedom cannot be construed as imposing on a State a positive obligation to disseminate information of its own motion.[149] The Government's primary duty is thus not to interfere with communication of information between individuals, be they legal or natural persons.

[145] R. Strand and M. Kaiser, *Report on ethical issues raised by emerging sciences and technologies,* University of Bergen, 23 January 2015, 39.
[146] See www.coe.int/bioethics
[147] *Hertel v. Switzerland*, no. 25181/94, § 50, ECHR 1998-VI.
[148] *Loiseau v. France* (dec.), no. 46809/99, ECHR 2003-XII.
[149] *Roche v. the United Kingdom* [GC], no. 32555/96, § 172, ECHR 2005-X.

This does not mean that States may deny access to relevant information arbitrarily. Complaints concerning a denial of access to information which is of importance for the applicant's personal situation have been generally examined by the ECrtHR under Article 8 of the Convention which guarantees the right to respect for private life and family life.

1. Everyone has the right to respect for his private and family life, his home and his correspondence.
2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic wellbeing of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.

In a number of cases the Court found that this article imposes upon the authorities a positive obligation to disclose to the applicant relevant data in order to be able to participate in decisions. For example, this was the case where applicants sought access to information about risks to one's health and well-being resulting from environmental pollution[150], or information which would permit them to assess any risk resulting from their participation in nuclear tests (so called Christmas Island nuclear tests) [151] or tests involving exposure to toxic chemicals (the so called Porton Down tests)[152]. The Court held, in particular, that a positive obligation arose to provide an "*effective and accessible procedure*" enabling the applicants to have access to "*all relevant and appropriate information*".[153]

And from a combination of article 2 that protects the right to life and article 8 the Court has construed a range of positive obligations for states to regulate and control hazardous activities (whether public or private) and enforce such regulations.

1. Everyone's right to life shall be protected by law. No one shall be deprived of his life intentionally save in the execution of a sentence of a court following his conviction of a crime for which this penalty is provided by law.
2. Deprivation of life shall not be regarded as inflicted in contravention of this Article when it results from the use of force which is no more than absolutely necessary:
(a) in defence of any person from unlawful violence;
(b) in order to effect a lawful arrest or to prevent the escape of a person lawfully detained;
(c) in action lawfully taken for the purpose of quelling a riot or insurrection.

Of particular importance for our discussion is that States must provide access to information on serious risks (in some instances they may have the duty to inform affected parties) and they must secure both public participation in decision-making and access to justice.[154] To comply with article 8, affected individuals must be able to participate in the decision-making process: first, information concerning risks must be available to those who are likely to be affected and, and second such individuals must also be able to appeal to the courts, against any decision, act or omission where they consider that their interests of their comments have not been given sufficient weight in the decision-making process.[155] In this way the Court has assigned a considerable amount of human rights work to the Member States.

Conclusion

For the time being I prefer this rather incremental way of creating 'new' human rights by interpreting and applying[156] the already existing and more encompassing human rights framework to approving new binding international law instruments. If judged necessary, this jurisprudence can be complemented by soft international law. This may not be the ideal way to proceed, but looking back in the past it seems the most pragmatic and promising way for the future.

[150] *Guerra and Others v. Italy* [GC], no. 14967/89, § 58 and 60, ECHR 1998-I.
[151] *McGinley and Egan v. the United Kingdom*, nos. 21825/93 and 23414/94, § 98 and 101, ECHR 1998-III.
[152] *Roche v. the United Kingdom* [GC], no. 32555/96, § 157 and162, ECHR 2005-X.
[153] *Roche v. the United Kingdom* [GC], no. 32555/96, § 162, ECHR 2005-X.
[154] T. Murphy and G.O. Cuin, 'Works in progress: new technologies and the European Court of Human Rights', *Human Rights Law Review*, 2010, 624.
[155] T. Murphy and G.O. Cuin, 'Works in progress: new technologies and the European Court of Human Rights', *Human Rights Law Review*, 2010, 625.
[156] Of course it is essential to bear in mind that the Court is not a legislature and that it should be careful not to assume legislative functions. See for this discussion *inter alia* E. Voeten, 'The politics of international judicial appointments: Evidence from the European Court of Human Rights', *International Organization,* 2007, 669-701.

Session 6 – Conclusions
Closing

Mr Jean-Yves Le Déaut

General Rapporteur on science and technology impact assessment of the Committee on Culture, Science, Education and Media of the Parliamentary Assembly of the Council of Europe (PACE)

Ladies and gentlemen, dear colleagues,

It is my honour to close this conference on emerging technologies and human rights and I would like to thank the Belgian Chairmanship of the Committee of Ministers and the Committee on Bioethics (DH-BIO) of the Council of Europe for organising it so perfectly.

As Head of the French Parliamentary Office for the Assessment of Scientific and Technological Choices (OPECST) and a Doctor of Sciences, I am currently the General Rapporteur on science and technology impact assessment of the Parliamentary Assembly of the Council of Europe.

Throughout 2015 I will also be chairing the European Parliamentary Technology Assessment Network (EPTA).

The OPECST contributed to the debates on the French laws on bioethics of 1992-1994, 2002-2004 and 2011. I have also been the OPECST's rapporteur for studies on biotechnologies, particularly on GMOs (I was behind the first conference of citizens on the subject in 1998), scientific knowledge and measures taken with regard to the transmission of the AIDS virus in 1993, asbestos in 1997, the impact of nanotechnologies in 2007, the impact of the use of the pesticide kepone in the West Indies in 2007, the security of information systems in 2013, drones in 2014, global warming in 2006 and innovation in the face of fears and risks in 2012.

I. SCIENCE AND TECHNOLOGY HAVE A GROWING IMPACT ON SOCIETY.

The political authorities have not sufficiently acknowledged the growing influence of science and technology on society, and these matters, which are often causes of controversy, should be dealt with as a matter of priority. Unfortunately they are used as means of political manipulation in France and in Europe. The issue of GMOs is an example of this. GMOs were grown without the slightest problem until 1996 in Europe and in many other parts of the world, but they were sacrificed in order to give a reply to certain national ecological movements without any real assessment of their impact on public health or the environment. The only issue which would have merited some special attention, namely the fact that intellectual property in living organisms was being appropriated by a few global firms, was largely ignored.

In the middle of the media storm surrounding mad cow disease, in 1996, the French newspaper Libération published a front-page article entitled "Mad soya invades Europe", suggesting that these supposedly inherently dangerous products deriving from transgenesis were about to come pouring into our plates. The controversy grew steadily with the media coverage of the crop destruction campaigners, the *faucheurs volontaires*, and ultimately GMOs became a hot potato for successive governments, serving as a scapegoat at the Grenelle Environment Round Table in France. Research on embryonic stem cells is another example. Whereas it is generally acknowledged that there is a need to foster scientific progress to find out more about the first stages of cell development, in 2011, French politicians prohibited research in embryonic stem cells under pressure from fundamentalist members of the National Assembly, who equated research on such cells to the destruction of embryos, which is of course an inaccurate representation, as no embryo may be created in France or in Europe for research purposes, and researchers work on cell lines or cells taken from supernumerary embryos which are due to be destroyed. These examples show that technology assessment procedures should be applied more widely before legislation is introduced so that conflicting evidence can be compared and contrasted.

II. LAW-MAKERS FACED WITH THE PROBLEM OF PREPARING LEGISLATION ON SUBJECTS THAT ARE CONTINUALLY EVOLVING.

In France, the final articles of the Bioethics Laws of 2004 and 2011 state: “This law shall be reviewed by the entire Parliament …”. The task of assessing the implementation of the law and the advisability of revising it was assigned in particular to the OPECST and the National Ethics Advisory Committee. This was a new legal concept, an open-ended law designed to lay down not intangible rules but what might be termed “biodegradable” ones, in other words rules that could be amended, some of which were destined to vanish entirely.

This is just an image of course, as there are intangible principles in bioethics, such as the pre-eminence of respect for the human body and its components and their inalienability and non-commercialisation, the ban on reproductive cloning and modification of the human genome, respect for privacy and personal data, non-discrimination with regard to genetic heritage, equitable access to care, free and informed consent including protection of persons not capable of consent, non-selection of sex and regulated organ transplants or research on embryonic stem cells.

The **Oviedo Convention** (1997) and its additional protocols have incorporated these principles. However, new technologies, and hence new questions, are emerging. Several key terms and concepts sum up the content of the debates at this symposium including convergence, the balance between innovation and precaution, human rights, globalisation, protection of personal data and privacy, and governance and public participation.

III. CONVERGENCE BETWEEN DISCIPLINES RESULT IN NEW INTERFACES

Convergence between disciplines is now the rule. They bring together nanotechnologies, biotechnologies, information technologies and the cognitive sciences. Everyone recognises that science is the driving force of progress but many of you, like Ms. Forus, have stressed that the innovation race raises the question whether the current legal framework is suitable and adequate.

We have moved on from a **treated human being** to a **repaired human being** and what is looming on the horizon now is an **enhanced human being**. This development raises new ethical questions owing to the new interfaces it creates between humans and machines or humans and molecules. The law must make it possible for individuals to resist pressures or constraints to become subject to technologies which would improve their performances in areas such as sport and games but also at work.

One of the main features of these new technologies is the scale of the changes they are bringing about. Not only are the boundaries between the medical and the non-medical fading but also, and even more markedly, those between the natural and the artificial. Through synthetic biology, we are able to recreate life from reconstituted molecules and we are capable now of crossing the barrier between the inert and the living. In the past we were concerned about transgenesis but now it is atoms, molecules or systems which we can eliminate or interchange. Genome editing now makes it possible to rewrite genes and could ultimately modify the germ line.

During the debate, several of you also highlighted the **irreversible and uncertain** nature of these developments. Having focused on the convergence which affects the boundaries between disciplines our debate moved on to the issue of the **balance between innovation and human rights**.

The impact of technology on society is complex and unpredictable so there is a need to strike a better balance between the future of science and ethical thought.

Applications are outpacing knowledge and not enough time is being taken to gauge the effects of new technologies. In some cases, technology transfers have undoubtedly been too rapid. In the case of nanotechnologies, some applications are being marketed only 18 months after the research has been completed.

On the other hand, controversy is slowing down innovation. The examples of GMOs and the crop destructions which have occurred in some countries and the debate over the effects of electromagnetic waves illustrate this point. Of course, the law in these areas eventually stabilises but

the period of legal proceedings and appeals is long. There is therefore a need to strike the right balance between the principle of precaution and the principle of innovation, for any country which rejects progress is doomed to fail. The purpose of innovation should be to improve both economic and human or social progress.

Progress therefore must be mastered. This idea was summarised perfectly in a description which I discovered when visiting the University of Louvain La Neuve, which said that innovation should be in the service of society and it is then and only then that **innovation becomes responsible.**

IV. GLOBALISATION HAS RADICALLY ALTERED THE EFFECTS OF SCIENTIFIC AND TECHNICAL PROGRESS.

The changes which we are currently witnessing cannot be separated from the **international context.** Legislation and regulatory potential vary from country to country. For instance, genetic testing is authorised not only in the United States but also in Spain and Germany. Medically assisted procreation (MAP) or surrogate motherhood is accepted in some countries and rejected in others. Research on embryonic stem cells may be accepted or prohibited. In some countries, exceptions are made. The controversy over genetically modified organisms (GMOs) has split the world, with many countries approving this technology and others rejecting it. In these cases, legislators have little say when faced with the power of multinationals. The world is also split by the digital divide and by unequal access to the Internet. These global disparities are all the more flagrant where it comes to equitable access for all to medicines and health care. Professor Jan Helge Solbakk of the Oslo Centre for Medical Ethics sums the matter up well when he says that **progress is not synonymous with universal access**. Progress must not only be controlled but also be shared. However, these questions fall well outside the traditional sphere of ethics. They will most certainly have a more serious impact in the future, with the mass storage and processing of data, the development of the Internet of things and all the technology which allows for remote surveillance.

V. GOVERNANCE MUST BE GEARED TO MORE ACTIVE PARTICIPATION BY CITIZENS.

The debate must not be monopolised by experts. An exchange must be organised between politicians, experts and citizens. Science and technology cannot contribute to progress unless, at the same time, there is **democratic progress**. By allowing citizens to take part in the debate we help them to enhance their understanding of subjects which are frequently complex. There is therefore a need to improve education in this area. Public debate should also be better organised. Often, radical or industrial lobbies try to stand in for the public to promote their own ideas. In our opinion the most effective debates are **open, collective exchanges of differing views**. The experience of the OPECST shows that citizen conferences can also shed an instructive light on matters. We have also come to the conclusion that technical and industrial scientific culture is not sufficiently well disseminated in France. Lastly, we regret that the media focus on controversial issues and do not go into the real substance of matters. The example of the rat poisoning tests made public by Gilles-Eric Séralini in 2012 with a great flurry of accompanying media attention (publication in major weekly news magazine, TV programme, publication of a book on the subject, etc.) illustrates this tendency. The risk of blanket media coverage is that discussions will be reduced to Manichaean viewpoints with no real exchange of arguments. Instead we should be organising in-depth debates on the advances of new technologies.

On this question, we held a public hearing in France in 2012. This presented an opportunity to take stock of several aspects of the controversy, of the links between GMOs and tumours and of the necessary statistical weight to guarantee the reliability of a study. Unfortunately, these debates could only be held ex post facto, whereas they should have been held before articles were published which had of course influenced public opinion on the subject.

I also think that it is wrong to oversimplify the meaning of terms such as “GMOs” and “nanotechnologies” as there are as many genetically modified organisms as there are events which lead to changes in a living organism or a gene. Likewise, we should not use the generic term “nanotechnologies” without specifying the circumstances in which a product deriving from nanotechnologies is used. Otherwise, all nanotechnologies could be vilified, as is the intention of the poster published by a highly active French radical association “*Pièces et Main d’Œuvre”*, which describes nanotechnologies as “Those little things that mess up our lives”.

In some ways, **our ideas about science and technology are the victims of socio-technical imaginings**. In our view, it is only after a debate that political leaders should establish scales of values in relation to human rights.

VI. NEW TECHNOLOGIES RAISE NEW ETHICAL QUESTIONS

It is quite clear that reproductive cloning of human beings should be prohibited and that new techniques making it possible to make lasting changes in the human genome raise major questions. Is it acceptable for example to allow definitive modifications to be made to germline cells?

These ethical values must be established by embracing prevention, a culture of safety and precaution, warning systems and different regulations according to the sectors concerned (research, healthcare, economic activities). There should be an ongoing comparison of risks and benefits, a balance between the advances hoped for and the need to respect individual freedoms or to respect the rights of individuals compared to those of society (the latter point being illustrated by vaccines).

New technologies are emerging. It is now possible to interfere with cognitive and cerebral processes in a way that undermines our freedom of thought, opening up the door to totalitarianism. Our identity and our integrity are threatened on an individual and a collective level by persuasive technologies and by technologies modifying our behaviour and our personality.

A recurring theme in science fiction is gradually becoming a reality, namely artificial intelligence, which raises formidable legal and ethical questions, particularly as regards responsibility for the acts of "robots". In a near future, we may have driverless vehicles, automated healthcare provided by autonomous robots and what might be termed humanoid home caregivers. Progress in genetics and medicine may also lead to directed and adapted modifications of the genome or make the concept of "cyborgs" a reality through machine-men transplantations.

Robots are going to acquire ever more capabilities and humans are going to be able to increase their capacities by boosting them through the contribution of machines. As I said before, "enhanced humans" may take over from "treated humans". We know how to set up functional brain-computer interfaces. All these changes are being speeded up by combinations of various technologies, in other words the aforementioned convergence between neuro, bio, information and cognitive sciences.

These matters would warrant a forward-looking debate by the Parliamentary Assembly of the Council of Europe as they will influence human rights and freedoms. Emerging technologies pose challenges linked to the complexity of these technological changes.

The use of these converging technologies for military purposes should lead to Council of Europe proposals concerning changes in governance. It should be pointed out that relatively recently, the Council of Europe has played a leading role in establishing a legal framework for bioethics. It is desirable for it to continue to act as a watchdog because dignity, identity, integrity, the right to privacy and freedom of thought should remain our priority.

Deep brain stimulation raises key questions. There is a legitimate fear that it may have side effects because so little is yet known about the functioning of the brain. What should we think about these techniques if they are used to improve people's moods or memory? These questions also apply to treatments using brain stem cells.

A person's integrity may be undermined if he or she is pressured into being subject to procedures to improve his or her capacities.

Insurance companies are tempted to adjust their premiums according to their clients' genetic heritage. The collection, comparison, analysis and use of biomedical data should, in my view, be regulated.

Respect for privacy is affected by the bulk collection of personal data or big data and their selective mining for commercial purposes to serve the interests of multinationals.

As certain recent events have shown, remote surveillance, electronic interception and the accumulation of data through the Internet of things call for the negotiation of international conventions and a commitment to greater transparency.

More generally speaking, the question of artificial intelligence and the use of robots raises new ethical and legal issues. I am going to propose that a Council of Europe report should be drawn up on this question.[157]

CONCLUSION

This conference on **emerging technologies and human rights,** held in Strasbourg by the Council of Europe has opened up lines of reflection which we should keep open. It has given us an opportunity to take up some of the recommendations of the rapporteurs from the University of Bergen and the Rathenau Institute in the Netherlands, to which I would add others.

1° **Better understanding makes for a better choice.** Action must be taken from school age on through education, and technical, scientific and industrial culture must be disseminated.

2° **Dialogue must be established between experts, politicians and citizens**. Many speakers called for the public to be involved in governance. Personally, I think that scientists have often deserted the public arena, leaving the space open to people who have vested interests in acting. The upshot is a kind of inward-looking debate in which the decision-makers and experts take the decisions, sometimes without any real dialogue, under pressure from lobbies. There is a need to diversify the sources of expertise and more fully integrate the human and social sciences into discussion groups. The media should also be involved in the debate to help them to avoid the trap of one-sided treatment of complex subjects.

3° **The current legal framework is inadequate.** The Oviedo Convention was a visionary text which grasped very early the links between technological development and fundamental freedoms. However, I do not share Professor Nys's view that the Convention does not need to be amended and it is enough to rely on the case law of the European Court of Human Rights in this sphere. Case law has a major part to play but it is not enough in itself in relation to issues that are constantly evolving, as it places the legislator in an awkward position. **Fundamental freedoms are protected when the rule of law is recognised.**

In my view, we have every reason to tackle these new challenges, particularly in the area of neurotechnologies, personal data collection and the modification of the genome.

The Council of Europe is due to draw up a White Paper in this field but this is only a first step because I believe that the Council of Europe committees, the national parliaments and the European Parliament should also be taking up these new challenges, organising open public discussion forums and fostering exchanges between experts holding different views. In short, **the fabric of laws should be shaped as far back up the line as possible.**

Some have raised the question as to whether a new convention on emerging technologies should be drawn up. This question must remain open but in my opinion, **there is probably not enough material for a new convention because convergence brings together the medical and non-medical fields.**

As has been done with the bioethics laws in France, it would be useful to **review the Oviedo Convention,** to add additional protocols to it and then, as Professor Semplici has suggested, to broaden the scope of its recommendations to take in the emerging and converging technologies. This will be a vast undertaking but I believe it to be necessary.

4° **There is also a need for improved co-ordination** between the action of the Council of Europe and its human rights work with that of the European Union – through the Parliament and

[157] On 29 September 2015, the Committee on Culture, Science, Education and Media of the Parliamentary Assembly of the Council of Europe appointed Mr Jean-Yves Le Déaut (France, SOC) Rapporteur on "Technological convergence, artificial intelligence and human rights" (Doc. 13833).

Committees – and with the national parliaments. The European Parliamentary Technology Assessment Network (EPTA), of which both the Parliamentary Assembly of the Council of Europe and the Rathenau Institute are members, has prepared an outstanding introductory report and might be one of the settings in which public hearings could be held bringing together experts, politicians and citizens.

5° In the recent past, the Council of Europe, and the DH-BIO in particular, have played a key role in establishing a legal framework for bioethics. The Assembly must **urgently take up the issue of the use of converging technologies for civil or military purposes**.

Mass data collection, particularly in the spheres of the genome or big data, can lead to violations of fundamental rights. Measures must be taken therefore to ensure the transparency of collection procedures and to work towards the sharing of these at least with the governments concerned.

6° I would also advocate **working on questions of ethics, science and technology in conjunction with UNESCO** so as to harmonise recommendations at international level.

On all these new, unpredictable subjects and complex issues, **the Council of Europe has a key supervisory part to play** as the dignity and integrity of human beings and respect for their private lives and freedom of thought must remain our priority.

We must help to **build a world in which technological progress is placed at the service of our values.**