

Knowledge transfer from citizens' panels to regulatory bodies in the domain of nano-enabled medical applications

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Abstract

Science and technology policy is increasingly subject to public scrutiny and to the mechanisms of public participation and deliberation. While such debates are valuable in terms of inciting communication, democratic deliberation and reflection on complex socio-technical problems among a potentially wide range of actors, they are more problematic – or at least challenging – from an ethical and a regulatory perspective, as it is not immediately clear how regulation can benefit from them. The outcomes of a citizens' panel on Bio-on-Chip technology, held in the Flemish participatory Technology Assessment project 'Nanotechnologies for Tomorrow's Society', clearly illustrates this point. Citizens express enthusiasm, skepticism and anxiety – and thus ambivalence – towards nanotechnologies, and ambiguities prevail in their usage of terms such as privacy and autonomy and in their weighing of moral claims and counterclaims. Yet regulatory agents and lawmakers desire unambiguous and clear wordings in their attempts to limit the possibility of different and inconsistent interpretations and to create a climate of 'certainty' in which technological innovation can thrive.

Picking up on this challenge, this paper explores possible ways of stimulating effective knowledge transfer from deliberation exercises to regulators in the domain of nano-enabled medical applications for human enhancement, such as targeted drug delivery systems, implantable biosensors and functionalized nanoparticles.

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In the first part, the authors unravel citizens' statements by linking these to the ethical principles of beneficence, nonmaleficence, autonomy and justice, which are rooted in consequence-based (utilitarianism), obligation-based (deontology) and justice-based moral theories (Rawlsianism). This principles' approach has previously been applied in biomedical ethics and has been expanded to biotechnology and food technologies.

In the second part, the authors turn on to the working conditions and aspirations of regulators in the current *upstreaming* of nanotechnology, using the ethical Technology Assessment approach as an illustration. This checklist approach refers to nine ethical aspects of technology: dissemination and use of information; control; influence and power; impact on social contact patterns; privacy; sustainability; human reproduction; gender, minorities and justice; international relations and impact on human values. The usefulness of such ethical aspects for the identification and analysis of needs for the construction of regulatory frameworks in the domain of nano-enabled medical applications is assessed.

To conclude, the authors advocate a knowledge transfer that benefits from a contextual ethical approach to analysis and emphasizes the constructive nature of deliberative lawmaking in which regulators are involved in technology assessment studies construct regulation along the road. As each actor can rely on a unique combination of knowledge, beliefs and values, the means by which the valuation of this context dependent information is performed has to be made transparent throughout the whole process of deliberative decision making in the domain of future healthcare. Effective knowledge transfer in the light of complexity, uncertainty and ambivalence therefore entails more than the movement of information from one actor to the other.

Introduction

Nanotechnology is generally defined as the understanding and control of matter at dimensions of approximately one to one hundred nanometers (UNESCO, 2006). Its development is embedded in a broader evolution towards the increased convergence of various natural science disciplines such as chemistry, physics and biology and engineering expertise. Healthcare is one domain which is expected to benefit immensely from the exploitation of novel properties at this scale. Real-time assessment of health status for accelerated clinical treatment, detailed imaging for more precise diagnosis, targeted drug delivery for improved treatment and regenerative medicine for healing beyond the normal capacities, are just some of the nano-enabled technology application directions in healthcare that are currently being investigated (EGE, 2007).

Nanotechnology developments are currently under intense scrutiny, not only from the side of nanoscientists, nanotechnology developers, business and policymakers, but also from the side of Science and Technology (S&T) scholars. Broader public involvement is a popular source of concern assessment. This involvement may be achieved on a number of levels ranging from risk communication over public opinion solicitation, to active participation of public representatives in the decision making process (Rowe & Frewer, 2000). While information and consultation are mainly about raising awareness and understanding based on knowledge transfer, public participation is more about engaging the public at various stages of technology development and implementation. However, public engagement is generally positioned by governments as restoring public faith in innovation and in regulatory oversight of science and technology (Kearnes & Wynne, 2007). Moreover, the present nanotechnology debate is dominated by the identification and classification of ethical, legal and social issues (ELSI) in relation to nanotechnological applications. Analyses of potential nanotechnology applications have led to the identification of a pool of ELSI that have a major overlap with concerns of other technologies, and a much smaller pool of ELSI that is expected to become important once nanotechnology will have reached a certain level of maturity (e.g., Ebbesen, 2006; Schmid et al., 2006; Schummer et al., 2007, Allhoff et al., 2007). Until now, however, much less attention has been given to how public responses to nanotechnologies and other lay inputs can be ‘transferred’ from public participation exercises to other stakeholders.

This paper specifically explores potential venues of knowledge transfer from public participation exercises to regulatory bodies and law makers in the domain of nano-enabled technologies for medical applications. It elaborates on the need to revise knowledge transfer not only as the movement of knowledge from citizens to scientists or vice versa, but to extend it with the integration of this knowledge into various levels of law. Hence, the knowledge generated from public participation and its subsequent transfer should be assessed continuously in view of its possible relevance for lawmakers. In what follows we utilize the substantive outcomes of a citizens' panel on Bio-on-chip technology² in the Flemish participatory Technology Assessment project 'Nanotechnologies for Tomorrow's Society' (NanoSoc) and probe its relevance for regulators.

What can the public provide? Lay ambivalences: experiences from the NanoSoc citizens' panel on Bio-on-chip

Nanotechnologies for Tomorrow's Society

NanoSoc counts as the largest Flemish Technology Assessment project to date.³ It is funded by the Flemish Institute for the Advancement of Innovation through Science and Technology for a four year period (2006-2010). Its core objective is to render nanoscientists and nanotechnologists aware of underlying assumptions, visions, expectations and concerns that guide nanotech research. This is done by confronting them directly and indirectly with a variety of societal perspectives, needs, and concerns, as voiced by stakeholders in government, industry and civil society and by ordinary citizens. To this end NanoSoc initiates four successive participatory rounds in which each actor is asked to contribute his (incomplete) views and perspectives in confrontation with those of others, ultimately with the aim of integrating societal considerations into scientific research agendas and day-to-day research practices. The first two rounds are

² In NanoSoc, the Bio-on-Chip case was loosely linked to a specific technological challenge: the merger of life-sciences with engineering, thereby combining the strengths of biological reactions and biochemical interactions with electronic signal detection and amplification. This merger is thought to lead to new applications in medicine, diagnostics and therapeutics that would never have been imaginable within the limitations of each domain separately. Hence, the Bio-on-Chip case exploits the coupling between electronics and biological components and aggregates the nano-enabled technologies for more advanced (i.e., more accurate, faster and more reliable) health diagnosis, monitoring, therapy and enhancement.

³ The first two authors are involved in NanoSoc as TA researchers.

“explorative”, as they are designed to ascertain which future nanotechnology trajectories actors deem plausible and therefore merit further consideration. The third and fourth round are “normative”; they consist of further interchanges with stakeholders and scientists respectively, and deal with the question which trajectories the latter consider worthy of elaboration, and if possible, of actual implementation. Importantly, these reflection rounds are initiated before and while nanotechnology trajectories are designed and implemented, as to allow for their timely adjustment and alteration. At present, the explorative phase within NanoSoc has been completed.

Citizens’ panel Bio-on-Chip⁴

In the month of September 2007, a citizens’ panel on Bio-on-Chip and nanotechnologies was held as part of the NanoSoc project. The panel consisted of approximately fifteen participants, who were selected on the basis of the principle of maximum variation, i.e., with the intention of bringing together citizens with the widest range of backgrounds as possible, thereby in all likelihood capturing the largest possible variety of viewpoints and values. Criteria for the selection included gender, age, socioeconomic status, work, and educational background.

Panelists were asked to reflect on two “nano-imaginaries”, understood as visionary scenarios situated around 2025, as constructed in interaction by participants to the first round of the NanoSoc project. The two imaginaries offered different fictive views of futures with Bio-on-Chip technology. They were not developed to have predictive value, but served to function as communication and reflection tools for participants of different backgrounds to become engaged in a debate about potential nanotechnology developments (Deblonde et al. 2008). To make the panel workshop as concrete as possible for the participants, the research team, comprising the project’s TA researchers, ethicists, nanoscientists, and two externally hired facilitators, had selected two scenes within each imaginary in advance, consisting of a relatively simple plot⁵ and one main character. In the panel workshop, the scenes were acted out by a professional actor and by participants themselves through low threshold role playing. For this purpose the panel was

⁴ This section is adapted from Van Oudheusden & Evers (2008).

⁵ A few themes which emerged in the Bio-on-Chip case related to fictitious experiences such as the first implanted chip, shopping and doing sports with implanted chips and a mother’s doubts whether to give her baby a chip implant and the subsequent impact thereof on her baby’s life quality.

divided into two halves. With one half of the group acting, the other half observed the play, after which both observers and players were asked to reflect on what they had seen and how they felt about the worlds they had “visited”. Questions laid out to the panelists included the following: How do these future worlds differ from the ways in which you live and work today? How are they similar? What role does technology play in these future worlds? Which values are at play in these future worlds?

Hence, the aim of the citizens’ panel was to engage citizens in fictive worlds to make explicit the values depicted therein and to have participants reflect on the changing nature of values over time. In the course of the panel workshop, citizens were also asked to specify more precisely the values they deemed most significant or prominent in these future worlds; this resulted in a list of approximately ten core values for each case. At the end of the workshop, the values list was further reduced to contain a number of three core values, as each panelist was asked to select the three values he or she considered most prominent of all. The lists served as empirical data for the ensuing ethical analysis, along with transcriptions *ad verbatim* of the various discussions between citizens about values during the workshops, all of which were held in Dutch. The methodology and results from the citizens’ panel on Bio-on-Chip are presented in the ensuing section.

Bio-on-Chip citizens’ panel analysis

The analysis of the citizens’ panel was conducted as follows. In a first phase, the most recurrent interpretations of values offered by panelists were listed and panelists’ statements were arranged according to established moral principles. To this end a ‘matrix for ethical analysis’ was deployed. In the second phase, a more in-depth assessment of panelists’ argumentation patterns and rhetoric was made, with the aim of doing justice to the multifaceted ways in which they make sense of technology in future health care systems.

Matrix for ethical analysis

The Ethical Matrix (EM) is a tool developed by Mepham (1996, 2006). It lays out a framework of moral principles and relevant interest groups that are affected by a particular technology. The EM can be deployed to pragmatically integrate the plurality of existing moral argumentations to reach a reflected ethical insight on a topic, basically by outlining and organizing factual and

normative claims in a debate. The principles that are used as critical directives for ethical reflections in the EM are wellbeing (non-maleficence and beneficence), autonomy and justice; they are based on the work of Beauchamp and Childress (2001), who have identified these principles as general norms guiding concrete actions and as *prima facie* obligations (i.e., one *prima facie* obligation must be fulfilled unless it conflicts with an equal or stronger obligation).

According to Kaiser et al. (2007), two main methodological approaches have emerged in adoption of the EM: a top-down and a bottom-up approach. In the first, the specifications of the four principles are largely set by the workshop organizers, while in the second, the participants specify the ethical principles and conduct the ethical deliberations themselves. In the latter, the organizers mainly defer to the majority views of the participants.

In NanoSoc both approaches were combined, by having panelists themselves extract values and disvalues in the course of the panel workshop (bottom-up), and by applying the formal structure of the EM retrospectively for the organization of empirical data (top-down). In other words, participants were not told in advance that the principles of nonmaleficence, beneficence, autonomy, and justice would be used as benchmarks to assess their argumentations, but were asked to freely draw out values from the nano-imaginaries presented to them.

In order to differentiate between our adopted EM and the framework as it was originally developed by Mepham, we use the term ‘matrix for ethical analysis’. An outline of the latter is presented in table 1. The rows of the matrix contain the four ethical principles. Arguments that deal with cost/benefit deliberations were placed under the heading of wellbeing, those that focus on the individual’s *modus vivendi* under autonomy and those that relate to individual or communal justice were placed under justice. The columns specify the actors that from our panelists’ perspective are to be challenged or affected by nanotechnologies: technology promoters, technology users, and regulatory governments. The category of technology promoters refers to nanoresearchers, companies and innovative agencies related to governments. It comprises statements made by citizens that somehow affect or involve technology promoters. Hence, it deals with citizens’ expectations about nanotechnology. Two columns (governments & technology promoters) list the expectations of citizens towards particular actors, while the other column (technology users) refers to the actual or potential impact of the technology on the actor. The latter category can further be divided into the personal and the societal environment. While

the personal environment aggregates statements concerning the impact of nanotechnology on an individual and on close relatives such as family and friends, the societal environment does so for references to actors that are more socially distanced from a technology user, such as school or the police.

Table 1 - The “matrix for ethical analysis” as deployed in NanoSoc

Moral actors		Expectations of citizens towards technology (promoters)	Expectations of citizens about technology users		Expectations of citizens towards regulatory governments
			Societal environment	Personal environment	
Ethical Principles		Statements that indicate respect and/or infringement of the principle at stake.			
Nonmaleficence	Well-being				
Beneficence					
Autonomy					
Justice					

To summarize, each statement was linked to a moral principle, an affected actor and a (dis)value. A value was defined as a desire. The opposite of a value – a disvalue – was defined as “that what is avoided” and hence, not intentionally sought and not pursued by citizens. Based on the value lists provided by the panelists and on our repeated listening to the audio recordings and reading of audio transcriptions, we identified a variety of values citizens considered significant. Subsequently, all values were listed in accordance with the moral principles (see table 2).

Table 2 - Values discerned in the citizens' panel on Bio-on-Chip

Wellbeing	Autonomy	Justice
Availability of BOC technology	Checks on scientific research	Financial capital
Carefree living	Freedom of choice	Financial access
Comfort	Independency from BOC technology	Distributive justice
Efficiency	Independency from people	Solidarity
Feedback provided by people	Individualization	
Feedback provided by technology	Prompt access to information	
Knowledge about the possibilities and risks of technology	Accountability	
Mental health	Self-governance	
Mobility	Societal control	
Personalization		
Physical health		
Quality of life		
Quality time		
Reliability of BOC technology		
Social status derived from BOC technology		
Trust in BOC technology		
Trust in the self-learning abilities of technological systems		
Trust in own abilities		

From de-contextualization to re-contextualization: values and argumentation patterns

The arrangement of values according to moral principles is both of procedural relevance (through the organization and visualization of values) and of substantive relevance (to understand how values relate to common moral principles). To give an example: the value of quality time - defined as the way in which a person makes use of his or her time to suit his or her own preferences - is placed under the rubric of wellbeing, indicating that we have deduced from panelists' argumentations that striving for this value is acknowledged by most to have a positive impact on an individual's wellbeing.

We are well aware of certain pitfalls in the value lists approach. Firstly, it entails the danger that ensuing discussions revolve too much around predefined issues and come at the expense of minority viewpoints. Secondly, although each value is catalogued under one moral principle, this value is often related to other principles as well. Thirdly, an ethical analysis such as this one fails to recognize how various values are deliberated and largely context dependent.⁶

Consider for instance the following citations provided by citizens.⁷

1 - The [technology] system is always to blame.(...) As an example look at GPS: if you are too late [for an appointment] it is the technology's fault

2- (...) as already is the case in our welfare society, people don't consider they themselves are to be held accountable (...). It is possible to conceive of a society in which there will be all kinds of lawsuits, because ultimately, [the user] bought an application which is supposed to be reliable, but it isn't and so I think that this will lead to [the emergence of] a new kind of person. Someone who expects that everything will be arranged for him.

As these citations indicate, panelists refer to 'accountability' (autonomy) and 'BOC technology reliability (wellbeing) as relevant values. Technology users are expected to shift accountability for an action (or an 'inaction') to the chip (citation 1) or to the organization that designed, developed, and/or implanted the chip in the body (citation 2). Accordingly, users will demand highly reliable and trustworthy technology applications, as well as prompt and effective service in case of malfunction. Not only do participants mention the impacts of technology on the ethical concept of 'accountability' (shifting acknowledgment and assumption of responsibility for actions and decisions from humans to technology), they also bring up the pro-active attitude of the empowered consumer (who expects and demands a high quality customer service) as pertaining to a new moral standard.

To partly overcome the problem of narrowing down too much the outcomes of this participation exercise to merely listing values, we look at the ways participants form and express opinions about new and emerging technologies in healthcare. For the purpose of this paper, we limit

⁶ For more on these considerations, see Van Oudheusden & Evers (2008).

⁷ The statements in this section are translated from Dutch and attempt to capture as much as possible the sense and tone of the original responses provided by citizens.

ourselves to taking a closer look at recurring argumentation patterns and responses. We draw inspiration from Swierstra et al. (2002), who discern four ethical patterns that reappear in connection to technological change: the precedent, the slippery slope, the habituation and the colonization argument. Based on the available data, the first three patterns are distinguished and illustrated below.

The *precedent argument* sheds light on argumentations that link present technology developments with past experiences. The participants of the citizens' panel explored future developments in medical health care drawing on present or past experiences. To offer an example:

I don't think you will have a [freedom of] choice in terms of [purchasing] a chip or not. Just like with so many things (...) you have no choice anymore. If you want an insurance or not - or with other things, this choice is not free. You can't say 'I don't want to if everybody else does it' If you look at the financial sector, everybody has to have a bank card or visa.

A *slippery slope argument* suggests that when an action or an event A - which in itself may be morally harmless or even laudable - is initiated, a morally unacceptable action or event B will necessarily or very likely follow as a result of sticky sequences of actions. One should therefore refrain from undertaking action A (Van Der Burg, 1998). The following quote illustrates a slippery slope argument. Screening, monitoring and therapeutic abilities of new (implanted) devices are widely investigated and will become available in the coming decades. Once an individual begins to use these devices (event A), his or her natural ability to deal with health anomalies weakens and may eventually disappear (event B).

"[...] everything [is] monitored, therefore (...) indicative symptoms of an upcoming flu will be treated in advance, while before, this was more laissez faire laissez passer (...) But what will happen if something goes wrong in this world, if that chip fails after all those years of control and intervention? If you then get the flu unexpectedly, you die. Thus, the conscious monitoring avoids the [intrinsic] abilities of the [natural] system to become self regulative (...) the idea of the [immune] system that is armed to deal with problems. You decrease the potential to deal with problems if e.g. you address your immune system too little or by not learning how to deal with unexpected circumstances (...)

In the previous extract, the perceived shift from trusting one's own abilities to relying on the technology is framed rather negatively. In the next passage – which more or less relates to the same topic – the negative consequences are not stressed. Rather, it is considered that people will not be aware of their reliance and dependency on technology. The excerpt can be seen as an illustration of the *habituation argument*, which refers to the gradual decline in (mostly negative) responses of the wider public towards technologies as technologies pervade ever more deeply into our daily lives.

(...) you rely completely on this [implanted chip for monitoring health status(...)] you don't think anymore, you just trust it. If you feel dizzy for instance, you will think that, as long as the chip doesn't signal a health problem, nothing is wrong. You will no longer trust your own instincts, the natural monitoring system that you naturally possess. (...) you will no longer be concerned with yourself and what you feel but you will trust something that is fallible (...)

Many verbalized statements express a tone emphasizing enthusiasm, skepticism, anxiety, uneasiness, antipathy and/or ambivalence. For the purpose of this paper we do not further elaborate each response category. Rather, we illustrate the category of ambivalence, which refers to a mixed or undecided appraisal of technology and its impacts on behalf of the respondents. Consider for instance the psychological effects of advanced monitoring diagnostics for medical purposes. On the one hand more medical information (or simply the availability thereof) could result in patients making better informed decisions. On the other, more medical information could lead patients to worry more about their health situation, especially in relation to domains that were previously not considered. Awareness without appropriate response itself has negative effects on the expressed desire for a carefree lifestyle.

"You don't need to worry too much about a fever or elevated blood pressure. It is monitored and [therefore] you don't need to be concerned. (...) Monitoring of a disease implies more possibilities and results in a higher quality of life."

"You will worry in advance about things that don't deserve your concern. The screening of newly born babies on hereditary diseases may result in anxious adults" (...) The sensor in my breast screening for cancer development, feels like a tumor.(...) In past times we didn't have much, and we were happier. Now everything is so complex."

If and then? Beyond the ethical analysis of the Bio-on-chip citizen' panel

As mentioned earlier, the (adapted) Ethical Matrix links values to the moral principles of wellbeing, autonomy and justice and sees these as essential to ethical decision making. This principles oriented approach presupposes the universal or objective nature of these principles. As these principles are considered to be binding on all moral persons irrespective of culture or creed, this approach is a particularly important tool for legislators and public policy makers, whose task is to regulate the conduct of various individuals, groups, and institutions with different background views and agendas (McCarthy, 2003). Nonetheless, moral justification is oriented towards these principles as 'any decision or course of action is morally justified *if* it is consistent with the relevant principle(s) and the derived specific action guiding rules'. Yet moral reasoning and practices obviously differ from culture to culture and even from person to person. As Tangwa (2005) has argued, an individual may recognize divergent perspectives on values, but he or she can never fully comprehend or grasp the other's motives for moral thinking and actions. Hence, if each value is placed under the heading of a single principle, this leaves little room for differing interpretations.

The principles oriented approach is for these reasons challenged by other ethical approaches such as narrative ethics, which states that 'every moral situation is unique and unrepeatable and [therefore] its meaning cannot be fully captured by appealing to law like universal principles' (McCarthy, 2003). While the moral justificatory force of *the* principles has a tendency of reducing disagreement, narrative ethics looks for methods and vocabularies for interpreting and respecting the unique and personal stories of individuals. Not only have doubts been articulated about the usefulness of principles in relation to more concrete judgments, but also about the suitability of a principles based approach for analysis and as advisory tool. Firstly, ethical frameworks and theories focus on intentional actions of individuals and therefore on individual responsibility, but unintentional consequences and collective decision making are rooted deeply in contemporary scientific and technological developments (Schomberg, 2007). In the citizens' panel on Bio-on-Chip, the tension between reduced will to be held accountable and the increase in individualized living patterns was assessed. Secondly, the use of standard ethical arguments such as slippery slope, precedent, colonization and habituation as analysis tools for argumentation patterns is controversial (Swierstra et al, 2002). While the first three arguments

fail to take into account that our morals change under the influence of new technologies, the fourth one conversely presents technological development as autonomous and as determined by an inner logic.

Yet, despite such limitations, we see great need and opportunity for the ethical analysis of arguments which indicate modification of values due to technological and/or societal developments. Consider for instance the following citation relating to the interaction between the value of ‘physical health’ (wellbeing) and subsequent technology developments and the impact on the values of ‘freedom of choice’ (autonomy) and ‘data privacy’ (autonomy):

“I hope there will be different chips for health purposes and for other uses, such as money transfers. So I think one will be faced with a choice between implanting a chip for health monitoring, and on the other hand, he or she will have to decide what the privacy implications are.”

As physical health is a dominant desire in our modern societies, Bio-on-Chip technology will be developed to further decrease anomalies in a person’s health status. In order to do this, chip technology will transfer data to different health care (related) databases. Measures will (have to) be operationalized to maximally guarantee the highly valued desires of ‘freedom of choice’ (autonomy) and ‘data privacy’ (autonomy). The diversification of chip technology into a wide range of applications in domains such as health and finances, will imply that an individual has to define the level of privacy for each chip activity. The value ‘data privacy’ may therefore shift from the perspective of a *right* to a *duty* and even a *burden*.

Engaging regulatory policy- and lawmakers in the nanotech debate

Regulation is something that is extremely difficult to define with certainty and clarity. In many cases this is due to the fact that its meaning and scope of inquiry is unsettled and contested. A theory (or model) of regulation is a set of propositions or hypotheses about why regulation emerges, which actors contribute to that emergence and the interactions between these regulatory actors. Theories of regulation can be broadly divided into three kinds: public interest, private interest and what may loosely be described as ‘institutionalist’ approaches. Public interest theories of regulation reflect a desire to pursue collective goals for the aim of promoting general welfare of the community. Private interest theories by contrast are largely explanatory in nature,

concerned with explaining how and why regulation emerges and why regulatory processes and outcomes take a particular shape and form. These theories of regulation are central to ‘private interests’ and attempts by these to secure regulatory benefits for themselves. The third theory, namely ‘institutionalistic’, tends to analyse regulatory approaches from the assumption that the state plays a significant role in regulation but it is also supplanted by a range of non-state mechanisms and actors like corporations and regulatory agencies, to name a few.⁸

Loosely put together, it can thus be said that regulation/law is more than simply setting up rules of precaution or restriction, it is also about ensuring public trust (public interest theories). Besides the general assumption that it is the role of law and regulation to maintain order and protect the general public from perceived dangers and risks; it is also seen by the public as an instrument that attempts to bring certainty in the midst of uncertainties, definition to the undefined and reason and rationality to the inexplicable. This however, is not the case as law cannot be said to be completely certain or explicable, but its role in maintaining public confidence and acceptability cannot be denied. An excellent example of this is the regulation of new technologies. There has been a fear of various technologies with varied levels of concerns in the eyes of the public over the years and many look at institutional initiatives or law and regulation as instruments through which these fears are addressed and a perception of regulatory certainty is seen. Hence, law and regulation has become an increasingly important tool to calm the fears of the public and assure it that steps are being taken to tackle its concerns. There is also the fear that if these public concerns are not addressed, it may lead to a complete rejection of the technology as is perceived in the case of biotechnology; the general fear being that if the public is not involved in the deliberative process and not taken into confidence, the same fate may befall nanotechnologies in general, irrespective of all the potential benefits. The biotechnology debate has also shown the importance of institutional guidance in a climate of technological and political uncertainty. The EU-study ‘Public Perceptions of Agricultural Biotechnology in Europe’ stated that ambivalent concerns of European citizens were mostly based on empirical lay knowledge about the past behavior of institutions responsible for the development and regulation

⁸ See in general, Bronwen Morgan & Karen Yeung (2007), *An Introduction to Law and Regulation : Text and Materials*, Cambridge University Press, pp. 306-312,

of technological innovations and risks (Marris et al, 2001). In other words, people need beacons of light when science is unable to provide answers about risks and possibilities.

However, in the case of technologies like nanotechnologies and other converging technologies, the general public perception is that law is generally playing catch or is lagging behind technological developments and that precautions have to be taken. There is skepticism on whether current law and regulation is *cautious* enough and anxiety on whether new forms of regulation will be *precautious* enough. Regulators and legislators hence have to first attempt to interpret these concerns, fears, perceptions and cautions from the public, which in many cases are seen as broad and ambiguous. This challenges the perception that law attempts to bring definition and a degree of certainty. Even though there is increased acceptance of the need to *upstream*, precisely what does this require remains ambiguous and open to several interpretations. Also, unlike legislators and regulators, publics are often more concerned with questions pertaining to control, ownership, ethics and responsibility (MacNaghten et al., 2005). This paper argues that rather than looking at these as ambivalent terms they should be seen as formations that link with established legal notions and principles. Uncertainties and ambivalences are now inherent in new technologies and law and legal processes will have to be flexible to reflect this.

Broadly speaking it can be said that there are four possible scenarios relating to the regulation of new technologies:

- a. Inadequate regulation: If societal concerns are not reflected and regulation of the technology is not attempted or is found inadequate; it may lead to catastrophic results as well as the likelihood of public rejection of the technology as a whole. This is hence not an option.
- b. Predictive regulation: Attempting to predict and regulate has severe pitfalls as it the risk of failure is high. It is almost impossible to predict with certainty the course a particular technology will take and its consequences. There is also the risk of being over-regulation.
- c. Responsive or reactive regulation: Formulating laws and regulatory structures as a response to immediate fears and perceived risks. This is a short term measure and also

likely to fail one because regulation would clearly be playing catch and it leaves the public open to unforeseen risks.

- d. Constructive regulation: Since it is unlikely that there will be a definitive form of regulation due to the various concerns and related ambiguities, a form of regulation will have to be ‘constructed’ that
 - i. Learns from past attempts to regulate new technologies and adapts accordingly.
 - ii. Addresses immediate issues and concerns and takes steps to neutralise these by implementing laws and regulation. Also reviewing existing regulations for gaps and taking necessary steps to address these.
 - iii. Analyses the whole *life cycle* of the technology. This would include the developmental process, patenting and marketing, and would tests the likely impact on individual and society.
 - iv. Broadens participation in the construction process. Here deliberative processes, ethical examination and knowledge gained from public participation would be transferred/ reflected. Deliberative processes invite revision in response to new moral insights or empirical discoveries.

Hence from the above it can be said that it is unlikely that law and regulation will be able to address the regulatory concerns of new technologies like nanotechnologies with absolute certainty; however what is possible, is the construction of a form of regulation that would attempt to reach a degree of certainty and acceptance. This should be seen as a process in itself that stays abreast with uncertainties rather than a fix. In order that this construction be meaningful, public perceptions and knowledge transfer from public deliberations should play an important and continuing role. Confronted with rapidly advancing and converging technologies, policy makers and regulators need to identify frameworks that are adaptive and anticipatory, yet which recognize the limits of prediction and accept the fact that uncertainties and ambivalence will stay in certain degrees.

To illustrate the importance of knowledge transfer and comprehend the critical role it can play in the *construction* of regulation, the ethical Technology Approach (eTA; Palm & Ove Hansson, 2006) is examined. This approach – though not an absolute one – uses a checklist method to nine ethical aspects/ concerns namely -dissemination and use of information; control; influence and power; impact on social contact patterns; privacy; sustainability; human reproduction; gender, minorities and justice; international relations and impact on human values. The checklist as such highlights critical issues and principles that are well accepted not only in public notions but also as well established legal principles. This paper draws on a few of these aspects from the checklist to reiterate firstly the fact that many of the public concerns are very genuine and have basis in well established principles and secondly they are also concerns that have challenged law and legal processes for a while.

Some of the principles from the eTA deal with issues relating to:

- a. Dissemination and use of information - New technologies have often given rise to new patterns for the dissemination of information. This has then raised questions about issues like security, privacy and data access. These concerns raised by the public or that are derived from public consultations are also well established legal concerns, hence these concerns can then be transferred to the legal processes. In the case of implantable medical devices concerns have been raised on issues pertaining to security, privacy, data access, data accuracy, device identification and software concerns. These issues already exist and challenge regulators and legislators. They being highlighted by public consultations and citizens panels help reflect their importance.
- b. Control, influence and power – relates to concerns such as who owns the technology, controls it and can hence influence it. Public concerns relating to patenting of nanotechnologies and inequalities arising from its commercialization (nano divide) would be examples.
- c. Privacy – An important issue is that of privacy. This is a major concern that is drawn out of most public deliberations on nanotechnology and other converging applications. This is also a well established and accepted legal right – the ‘right to privacy’.

- d. Sustainability - New technologies may affect all three sustainability dimensions through their influence on economical, social, and ecological development. The ecological dimension of sustainability is a common concern. The general public tends to be skeptical about the implications and effects of nanomaterials/ nanoparticles on the environment and so also the use of these nanomaterials and nanoparticles in medical applications and their implications on human health. These concerns interlink with legal challenges on protecting the environment and human health.

It can thus be seen that ethical examination and public perceptions can lead to a realistic and balanced approach to technology that leaves scope to be open to different perspectives, interests and solutions and to direct involvement in the developmental process. Such approaches attempt to apply generally accepted ethical theories and principles to specific problems and to offer solutions that are based on moral principles like: respect for autonomy, beneficence/non-maleficence and and justice. From these basic principles – ethical guidelines and rules (regulation) can be derived.⁹ The reflections and concerns that are expressed by approaches like the eTA enable a better understanding of the technology as well as public perceptions which can play an important role in law and regulation. Public involvement in exercises such as citizens panels go beyond identification of concerns; they offer opportunities for the public to be involved and to participate while at the same time giving legislators and regulators the unique opportunity to draw on knowledge of the participants and formulate regulations with less likelihood of objections. The goal is not simply to convince the public of the safety of new technologies but to ensure public confidence and trust based on the inclusion of public concerns in the legislative and decision making. Kearnes and Wynne (2007) state:

‘This [public consultation, engagement and deliberation] gives rise to the notion of ‘scientific citizenship’ where the public is seen as a genuine stakeholder that plays a role in the deliberative process and not merely as a problem that needs to be addressed by engagement’.

⁹ This is not to say, however, that ethics always precedes legislation, as it evidently concerns a two-way relation. If law is enacted properly and is not perceived to be unjust, it is likely to change views of people as to what is ethically acceptable or not (Hermerén, 2006).

Deliberative processes endorse principles which maintain that legitimacy depends on the degree to which those affected by it have been included in the decision making processes and have had the opportunity to influence the outcome; and must also invite revision in response to new issues and challenges (Farrelly, 2007).

Thus it can be concluded that nanotechnologies will usher in profound changes as well continuity with several issues and challenges that preceded it. An ethical approach provides a much richer perspective of these relevant issues, values and challenges that need to be taken into consideration in the political/ regulatory process- the challenge off course is to focus on issues and alternatives rather than mere rhetoric. The fact that the public have concerns should not be viewed as a lack of public trust rather it should be seen as enthusiasm and a reflection of anxieties and ‘ambivalence’ that can be re-thought, re-worked and used as a tool that can then form part of the *construction* of a form of regulation. In , *The Imperative of Responsibility*, Jonas (1985) advocates the need for a radically new ethics to rule our relation to the future in the technological age. Drawing parallels it can be said that the construction of regulation should reflect a new form of regulation, once that is not regulation *of* the future but regulation *for* the future.

Conclusions

Nanotechnology, and converging technologies in general, are strong enablers from a technological viewpoint for researchers and developers who are interested in exploring and exploiting novel dimensions for future healthcare. Yet, they are equally strong societal enablers, which compel society at large to scrutinize the potential and desirable outcomes of emerging society-embedded technological revolutions.

The first part of the paper illustrates a panel of Flemish citizens' responses to potential future applications of nanotechnology for medical purposes. It concludes that values – as what is desired in and through daily life actions – touch upon consequence, autonomy or justice based moral principles. Citizens use ethical arguments based on precedents, slippery slope and habituation in their rhetoric. While precedent arguments link some ethical worries and concerns related to emerging technologies with past technologies, habituation arguments illustrate the sensitivity of values to the interaction of technology developments and society. In other words, as technology emerges, it changes (some of the) values a society adheres to. Slippery slope arguments emphasize the inevitability of a negative outcome once certain socio-technical choices have been made beyond a point. Additionally, the panelists express enthusiasm, skepticism, ambivalence, activism, antipathy and uneasiness about possible or expected technological developments.

However, the ethical analysis is reductive and establishes a rather detached and even artificial connection between values and moral principles. Moreover, ethical approaches based on major moral theories largely fail to recognize the impact of technology as an enabler of the re-interpretation of values in a specific context. Autonomy issues such as data privacy and accountability are to be challenged by developments including remote home help systems and lab-on-chip screening. It is more fruitful to understand the context dependent nature of moral reasoning, than to limit the ethical analysis to the identification of data privacy or accountability as emerging ethical issues. We have argued that any such classification should be part of a more comprehensive analysis into the valuations of lay people's ambiguities and ambivalences leaving room for co-existing interpretations. Similarly, we have argued to abstain from narrowing down

the nanotechnology debate based on a list of ambivalent concerns and promises, but to base this on the valuation of information expressed by beliefs and values. As there will always be ambiguities and ambivalences, we have argued that regulators could benefit from taking into consideration the plurality of beliefs and value interpretations. The debates on nanotechnology, and converging technologies in general, is characterized by certainty about uncertainty and agreement on disagreement. And so it will remain. Simply recognizing the fact that there will always be ambiguities and ambivalences, may be the 'solution'. Regulators should therefore abandon their desire to reduce ambiguities and ambivalences. Finally, we contend that Technology Assessment studies should involve and include regulators, thereby enabling them to deal more appropriately with socio-technical complexity, uncertainty and ambivalence in future health care.

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