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Regulating Nanotechnologies: Risk Management Models and Nanomedicine

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Legal regulation has a substantial impact on the development of technologies. Depending on its scope, structure, and effectiveness, regulation can essentially shape the research, development, production, commercialization, and consumption of emerging technologies in various ways. The lack of regulation, or of corresponding enforcement, can lead to the infringement of rights, harm to workers, consumers, and the environment, and to the neglect of the public interest. On the other hand, too strict regulations, based on incomplete information or excessive caution, may equally cause harm by omitting the potential benefits or by distorting and delaying the technological development.

At the current stage, nanotechnologies affect many areas of law: occupational health and safety, environmental protection, consumer protection, medical law, privacy and civil liberties, intellectual property and patent law. Nonetheless, the analysis of the legal implications of nanotechnologies is just at the beginning. What is particularly needed is an overall view of the principles that can guide the legal approach. This *special issue* on Regulating Nanotechnologies aims to provide this kind of inquiry.

Up to now, a specific legal framework for nanotechnologies does not exist in any country. Of course, nanotechnologies can, in principle, be indirectly regulated by the laws already in force for different purposes. However, the question is whether and how much such existing norms and principles fit the challenges of nanotechnologies in particular, and of emerging technologies in general. What law, as a means for justice, is required to do is, for instance, to protect human health and the environment against the potential toxicity of nanoparticles; to guarantee a fair trade-off between intellectual property rights and public interest (or the right to health when medical devices and drugs are concerned); and more generally, to ensure that the technology is used according to human rights and to the principles of justice embraced by the societies and legal orders. Both those who think that emerging technologies (including nanotechnologies) should be regulated by existent norms and those who maintain the need for a specific regulation for nanotechnologies are to defend their position by answering some guiding questions: (1) Is

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there anything truly new about nanotechnologies that affects legal regulation? (2) Which risk management model should be best embraced for nanotechnologies? (3) How can legal regulation avoid harmful effects of nanotechnologies resting on incomplete risk information without casting the incomplete information in permanent law; how can the regulation be flexibly adjusted to continuously improved risk identification and assessments?

Many countries have now started programs to assess the ethical, legal, and social implications of nano- and nano-biotechnology, but the field is still in an early, while rapidly growing, state with certain shortcomings. In particular, integrating works that combine all three domains—ethical, legal, and social—are missing. The research tends to follow disciplinary lines of specialization and fragmentation, although the three domains obviously need to inform each other. Ethics cannot ignore legal and social constraints, social issues need to be assessed from ethical and legal frameworks, and legal regulation needs to consider both ethical principles and broader social issues.

For this *special issue* on legal regulations of nanotechnologies we have invited four law scholars from different countries who are all already distinguished experts in this young field with an ethical background and sensitivity to social issues. All contributors agree that the lack of sufficient scientific knowledge about the development, products, and potential uses of nanotechnologies is at the core of the issues. The first two papers, by Gary Marchant et al. and Gert van Calster, address the general question of which regulatory models or principles of risk management might be suitable for nanotechnologies. The second pair of papers, by Roger Brownsword and Giorgia Guerra, focus on specific regulatory issues of nanomedicine.

The paper by Gary E. Marchant, Douglas J. Sylvester, and Kenneth W. Abbott (Arizona State University) provides a critical survey of traditional risk management models and their weaknesses in dealing with nanotechnologies: acceptable risk, cost-benefit analysis, and best available technology. They argue that the high level of uncertainty in identifying risks of nanotechnologies makes any risk-based approaches unreliable. While cost-benefit analysis has the advantage of considering benefits besides risks, it only adds uncertainties about the benefits to the uncertainties about risks. If one avoids risk analysis (and debates) and defines regulatory standards through the best available technology that reduces risks to the greatest extent, this could under- or over-regulate the development compared to what would be considered acceptable risks. Moreover, relating regulatory standards to the state of the art might prevent companies from developing better (but more expensive) control technologies.

In the past decade, many have promoted the precautionary principle as the best risk management approach to deal with emerging technologies. Yet, at a closer look, it is much contested what the principle really consists in and how it can be implemented in regulatory systems. Thus, the precautionary principle has become the target of much criticism concerning its justification, scope, and definition. Critics, including most authors in this issue, argue for instance: the principle has been set down in many different versions and there is no standard text of it; because of its ambiguity, the precautionary principle is prone to arbitrary decision-making, fails to provide a true guidance in regulatory decisions and tends to increase public anxiety rather than help people participate in decisions; it is biased towards the status quo, is an inflexible regulatory tool, and its application does not allow to consider properly the advantages of new technologies. The debate over this principle is destined to continue, and it serves to promote a dialogue, both within the scientific community and the larger civil society, on what to do if risks have to be anticipated on uncertain scientific bases. In this sense, the principle would contain a proactive and pre-emptive approach to uncertain risks rather than a proper rule for decisions.

Against the background of the weaknesses of traditional risk management models, Marchant et al. argue to start with soft and decentralized regulations of nanotechnologies, such as self-regulation, that may gradually evolve to harder regulations as required. Such an approach is regarded to be flexible since it draws on different approaches for addressing risks and favors subsidiarity and decentralization; to promote transparency and dissemination of information; and to support active participation of stakeholders in developing and applying risk management norms. Their model rests on the so-called "responsive regulation" theory, which aims at overcoming the divide between regulation and deregulation (1) by identifying different systems of enforcement accord-

ing to the different issues to be regulated; (2) by stressing the importance of the synergy between public and private actions; and (3) by giving an important role to soft law, which becomes the first kind of regulation to be resorted to when information is scarce and risk identification highly uncertain.

Geert van Calster (University of Leuven), in reviewing risk regulation in the European Union, argues that what matters is how risk regulation models are implemented in practice rather than the definition of formal principles. To that end he compares the precautionary principle with the prevention principle in international law. The latter requires countries to prevent known risks from affecting other countries and is, unlike the precautionary principle, widely, though not globally, accepted. At first glance, the precautionary principle differs from the prevention principle because it deals with unknown or uncertain risks rather than known risks. Yet, the degree of uncertainty about risks varies in both cases to the extent that the two principles overlap. For instance, the precautionary principle may stretch from the weak version (maintaining that, when there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental deregulation) to the strong version (according to which, where an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause–effect relationships are not fully established scientifically).

Van Calster argues that cultural differences lie behind the different definitions and roles of the precautionary principle. This is true of the frequently stressed divide between the European Union and the United States on the regulation of emerging technologies: the difference between these perspectives goes beyond the role and definition of the precautionary principle and is rather about the overall administration of risk, which has been historically developed in different ways. He particularly questions the divide of labor that has emerged in the European Union and its Member States, according to which risk identification, risk assessment, risk management, and risk communication are neatly divided and in the responsibility of different subjects, such as scientists, regulatory agencies, and elected politicians. If only elected politicians are responsible for risk management, this becomes, according to van Calster, prone to recourse to the precautionary principle, because of the public perception of risks. Moreover, the increasing interdisciplinarity in nanotechnologies also requires that scientific risk identification and responsibility need to be shared and moved to the public sphere, rather than being assigned to disciplinary specialists. Van Calster argues for a more flexible way in the administration of risks in which different parties, including the public, are involved in each step.

The engagement of the public in risk regulation debates, although called for by the authors in this issue and many others, is not without difficulties. As van Calster points out, the public in the European Union seems to be not very interested in nanotechnologies yet, which may slow down the construction of participatory rule-making paths. Marchant et al., while emphasizing the need of considering the public perception of risks in their flexible regulatory model, analyze some of the problems. People have a tendency to develop rapidly, and sometimes automatically, positive or negative feelings when faced only with certain terms; they tend to overestimate the probability of harms they had personal experience with in the past; they sometimes encounter difficulties in considering risks and benefits at the same time; and they are prone to cascading effects when individual risk perception is reinforced by social interactions and the media.

Among all potential uses of nanotechnologies, the application to medicine, i.e. nanomedicine, stands out because it directly affects our health and well-being. Thus the regulation of nanomedicine deserves particular attention, as medicine has been treated by particular laws ever since. According to the European Technology Platform on Nanomedicine, three research areas are particularly important: diagnostic and imaging technologies, targeted drug delivery, and regenerative medicine. The application of nanotechnologies to healthcare is expected to highly improve diagnosis, treatment, and the follow-up monitoring of diseases. The main promises in this field concern both in vitro and in vivo techniques: nano-devices that may shift diagnosis into the pre-symptomatic stage and allow pre-emptive therapeutic measures, biosensors, implants, surgical tools, subcutaneous chips that are already being developed to monitor key body parameters, and hand-held diagnostic kits. However the general acceptability of nanomedicine is subordinated to the risk assessment of nanoparticles ingestion, inhalation, and absorption by human subjects and their

dispersion in the environment. In addition, as with other medical treatments, the individual acceptance of specific nanomedical treatments rest on the patients' informed consent, which in the case of uncertain risks poses new problems.

The paper by Roger Brownsword (King's College London) argues that the case of nanomedicine calls for a deeper ethical reflection on the moral principles in pluralistic societies, which legal regulations of medicine need to take into account. Like most of the other authors, he criticizes the current focus on the precautionary principle and points out that it detracts the attention from the underlying ethical conflicts, which he describes in terms of three rivaling bioethical positions: goal-orientated, rights-based, and duty-based ethics. Depending on their position in this "bioethical triangle", people hold different views in medical ethics on crucial issues, such as the role and interpretation of human rights, human dignity, precaution, and informed consent. Brownsword illustrates the ethical diversity first by analyzing important articles of the UNESCO Universal Declaration on Bioethics and Human Rights (2005). Applying his analytical framework to nanomedicine, he investigates crucial debates on such issues as commodification, enhancement, precaution, and informed consent under conditions of extreme uncertainty. Rather than presenting a simple solution, he argues that nanomedicine is likely to compound the legitimacy crisis of regulators because it reinforces the existing bioethical plurality.

Finally, Giorgia Guerra (University of Padova) asks whether the existing normative framework for medicine in the European Union is suitable for nanomedicine. The European Community initiatives and advisory bodies encourage member states to apply to nanotechnologies as much as possible the law already in force for new technologies, provided that health risks are avoided, consumers' confidence achieved, and conditions for responsible development of nanotechnologies created. Guerra's contribution analyzes whether these conditions are actually met, by scrutinizing current European regulation for new biomedical products, drugs, and chemicals. She argues that nanotechnologies already pose new problems regarding the classification of their products. Because of differences in the manufacturing of biomedical tools on the nanoscale compared to conventional methods, the number of combinations between different types of components increases, leading to greater numbers of final biomedical products. Nanoparticulate drugs generally suffer from a lack of standardized safety assessments, which questions the soundness of the existing regulatory framework. Furthermore, nanotechnologies produce indistinct effects that are not clearly classifiable as mechanical, chemical, or biological, so that nanomedical products do not clearly fall into one of the traditional categories of drugs, devices, and biological products, which are differently treated by law. Based on her analysis, Guerra stands up for a new specific regulation of nanomedicine and agrees with giving, at the current stage, an important role to soft law measures that include national and international guidelines, technical standards, and codes of conduct.

Something is further suggested, though not directly addressed, in the papers presented here. Apart from the problem if specific regulations should be laid down for nanotechnologies and how they should be formulated, it is important to guarantee harmonization among the regulative choices in the different legal systems and their ability to meet the standards and principles set down by international law. National differences in normative frameworks may cause biases in nanotechnologies research, frustrate international cooperation, and cause unequal global distribution of risks and benefits of nanotechnologies.