Deciding the Future of Nanotechnologies: Legal Perspectives on Issues of Democracy and Technology

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Abstract. What potential problems do emerging nanotechnologies present? Who should decide how, where, and by whom new nanotechnologies should be pursued and regulated? This paper begins with a brief review of two attempts to deal with issues such as those emerging alongside nanotechnologies. In the first, Frederick Fiedler and Glenn Reynolds draw attention to new technologies in the medical field. In the second, Paul Lin-Easton deals with environmental concerns over these new (potential) technologies. I use the concerns raised in these two law reviews to draw attention to issues that must be addressed if societies are to maintain control over the design and production of new technologies, including nanotechnologies. Specifically, I focus on issues of technological determinism, technology-society relations, and building a base for broad public participation in the creation, acceptance, and use of new technologies.

Introduction

The coming of the age of nanotechnologies has raised many new concerns and rehashed old debates in new guises. For present purposes, I would like to approach this topic from an often neglected perspective – that of the law. My intention here is not to offer an exhaustive or intensive look at the interrelations of nanotechnologies and laws, but instead to demonstrate how concerns raised in some corners of the legal world echo those arising from other sectors embroiled in this current debate – including issues of safety, risk, precaution, and public involvement in decision-making processes concerning emerging technologies. To that end, I will provide a look at two specific law reviews related to nanotechnologies. In the first, the authors – Frederick Fiedler and Glenn Reynolds – tackle the problem of classification of new nanotechnologies designed for medical use. Their review highlights the importance of dealing with conceptual issues at an early stage because the results of such seemingly mundane classificatory work can have dramatic resonance when it comes to determining who will have access to these technologies and under whose supervision these technologies will fall.

In the second review, Paul Lin-Easton deals more explicitly with issues of safety and risk with regards to pre-emptive regulation of nanotechnologies. His review outlines concerns raised by the possibility of these new technologies. To prepare for these, Lin-Easton advocates a modified use of the "Wingspread Statement on the Precautionary Principle" to propose how and under what conditions we ought to proceed in our research. Perhaps most importantly, Lin-Easton advocates the participation of a broader public in deciding how research should be carried out and to what end(s).

What role can/should the public play in decisions about nanotechnologies? I will close with a discussion of how the development of nanotechnologies might be more demo-

cratic. This will involve challenges to traditional cultures of expertise and the creation of spaces for public debate, dissent, and decision-making. To begin answering this question, we must first challenge the popular notion of technological determinism, which disempowers people by removing their agency from technological developments. An answer will also require a rethinking of relations between the 'social' and the 'technical' in order to view technologies not as something separate or distinct from the social but as inextricably linked to the social – creating what is sometimes called a 'sociotechnical' system. Finally, I'll discuss briefly what it might mean to have a 'democratic technology'. Drawing on the work of Andrew Feenberg, I hope to highlight what possibilities exist for the creation of technologies of production and dissemination that empower rather than disempower the public(s).

1. Nanotechnology and Medicine: Drug or Device:

In their overview of legal problems stemming from nanotechnology, Frederick Fiedler and Glenn Reynolds point out one important classification used by the government for regulatory purposes that may face serious challenges with the introduction of nanotechnology in the medical field: the distinction between "drug" and "device". Current legislation defines a drug as:

(A) articles recognized in the official United States Pharmacopeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). (quoted in Fiedler and Reynolds 1994, pp. 607-8)

And a device is defined as:

[A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is –

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes. (quoted in Fiedler and Reynolds 1994, p. 608)

In essence, then, the distinction between drug and device is a difference between chemical and mechanical operation (*ibid.*, p. 608). However, as Fiedler and Reynolds point out, the potential uses of nanotechnology in medicine blur this distinction. Often, the forces at work on an atomic scale are difficult to distinguish from one another. At this level, "it becomes virtually impossible to separate 'mechanical' from 'chemical' or 'electrical' effects" (*ibid.*, p. 609).

As an example, Fiedler and Reynolds discuss the potential role of "nanorobots" working to remove the atherosclerotic plaque from coronary arteries. Current methods for the removal of this plaque involve the use of "a variety of relatively small devices: wires, drills, balloons, and lasers, small enough to be inserted into the coronary arteries by catheter" (*ibid.*, p. 610). In the future, it has been proposed, doctors could use nanodevices for the continual removal of this plaque. These devices would operate by searching out plaque deposits and removing them metabolically one molecule at a time. The key question here, Fiedler and Reynolds point out, is *how* this removal will occur: chemically or mechanically. Current technologies, they argue, are already capable of similar actions. "Conceptually, nanorobots scraping away at arterial plaque simply represent a more refined version of current technology, and thus should be regulated as devices" (*ibid.*, p. 610). But, what if we view the action of the nanorobots not as scraping the plaque from the arterial walls, but instead acting as a solvent, dissolving the plaque? From this perspective, we may perceive the nanorobots to be drugs, metabolizing the plaque and drawing energy from the host cells (*ibid.*, p. 611). Our characterization of the plaque, too, may prove important in deciding how to classify these nanorobots: "If the tiny bits of atherosclerotic plaque are individual cholesterol molecules or individual calcium atoms, then there is cause for uncertainty over whether an action is chemical, mechanical, electrical or otherwise" (*ibid.*, pp. 610-11).

Does it really matter whether or not we understand fully how these actions occur? What concern should we have if little nanorobots don't fit neatly into our current schemes of classification? Fiedler and Reynolds argue that in these early stages it is of the utmost importance to deal with these conceptual issues: "While in an academic sense, or even a practical one, it may not matter whether the action of such nanorobots is conceived of as chemical or mechanical, it is very important in a legal and regulatory sense, at least until regulators begin to take cognizance of nanotechnology in an organized fashion" (*ibid.*, pp. 611-12). Finding ways to deal with these issues will be crucial as new products begin to enter markets. Often, the time during which new technologies begin to enter the market-place overlaps with an unprepared legislative structure – and, I would argue, an unprepared public. Fiedler and Reynolds note that: "For emergent nanotechnology, there will most likely be a window during which the old laws will lag behind the new technology. Within that window opportunities will arise for mismanagement of new products" (*ibid.*, p. 612).

If the current language of the laws pertaining to drugs and devices fails to accommodate nanotechnology, Fiedler and Reynolds suggest preemptive changes to the wording of such laws to help alleviate some of the possibilities for mismanagement. In place of a classificatory system based upon how the technology operates (*i.e.*, "force oriented"), the authors suggest a functional approach to regulation. Functions could be divided into three categories: repair, "the restoration to a previous normal state, analogous to bonesetting or suturing a cut"; replacement, "like organ transplants or the introduction of artificial joints"; and augmentation or enhancement, "the truly novel situation ... in which cells are programmed or modified to perform in ways not called for by nature" (*ibid.*, p. 616). These three functions are analogous, the authors contend, to current medical procedures, and could thus be accommodated easily within the medical and legal institutions. Additionally, each of these three functions could be regulated differently – with repair being the most loosely regulated and augmentation requiring the most oversight.

The legal concerns related to the use of nanotechnology are not limited to classification and regulation. Additional effort will be required to deal with, for example, whether or not nanotechnology should be patented like hardware or copyrighted like software (*ibid.*, pp. 613-4, 619), the maintenance of regulatory competence (*ibid.*, p. 618), how insurance companies will treat nanotechnology in medicine (*ibid.*, p. 622), and threats to notions of personal identity (*ibid.*, pp. 623-624).

Aside from the legal concerns raised by Fiedler and Reynolds with respect to the introduction of nanotechnology into medicine, some environmentalists and environmental lawyers are concerned about unforeseen challenges that this new technology may present for them.

2. Nanotechnology and the Environment: Pleas for the Precautionary Principle

In addition to the often optimistic outlook offered by those working in the nanotechnology field, some scientists and environmentalists are concerned about the unintentional consequences that these new technologies may have on the global environment. In his 2001 law review, "It's Time for Environmentalists to Think Small – Real Small", Paul Lin-Easton issues a call for environmental lawyers to get involved in the development of anticipatory precautionary principles to be applied to nanotechnology research, design, and manufacturing. In particular, the author develops a policy plan modeled on the "Wingspread Statement on the Precautionary Principle". The Wingspread Statement asserts three principles that should be followed when dealing with potentially harmful agents:

Where an activity raises threats of harm to the environment or human health, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.

In this context, the proponent of an activity, rather than the public bears the burden of proof.

The process of applying the Precautionary Principle must be open, informed and democratic, and must include potentially affected parties. It must also involve an examination of the full range of alternatives, including no action. (quoted in Lin-Easton 2001, p. 121, note 100)

Lin-Easton divided these three principles into four, and applies them to the issue of nanotechnology. First, the proponents of nanotechnologies should bear the burden of proving its safety; conversely, opponents should not have to demonstrate its harmfulness. Second, all alternatives to nanotechnologies should be explored before the decision is made to proceed; this includes the option of relinquishment of the technology. Third, governments, businesses, and individual researchers involved in nanotechnology research, design, or manufacturing have a duty to prevent harm by taking anticipatory action. And fourth, the application of the precautionary principle must proceed in an environment that is open, informed, and democratic (Lin-Easton 2001, p. 123). These four points provide the structure for the remainder of his article, and I will discuss his views on each.

2.1 The Burden of Proof

As stated above, the precautionary principle places the burden of proof upon the proponents of nanotechnology. Additionally, those involved with the development or production of nanotechnologies – governments, businesses, or individuals – will be held responsible for any damage caused by these technologies: "This responsibility includes financial responsibility in the form of assurance bonds and tort liability, and a duty to 'routinely monitor their impacts, inform the public and authorities when a potential impact is found, and [to] act upon that knowledge'" (*ibid.*, p. 123).

Opponents of the precautionary principle often draw attention to the fact that nothing can ever be proven completely safe, and that this position simple declares nanotechnology to be guilty until proven innocent. Proponents of the use of the precautionary principle do not see this as an absolute ban, but an assurance that development objectives include not only economic goals, but also ecological and health considerations (*ibid.*, p. 123).

2.2 Relinquishment

The second principle discussed by Lin-Easton states that when evaluating nanotechnology, all alternatives must be considered, including relinquishment. Relinquishment is the position that has been advocated by Bill Joy in his *Wired* magazine article "Why the Future

Doesn't Need Us" (2000). It involves the abandonment of a research project if engagement in that research threatens the environment or human health. Much of this sentiment stems from what many see as the tremendous potential for catastrophe that nanotechnology possesses. And while scientists involved with nanotechnology research may be uncertain about the potential dangers of this emerging field, proponents of the precautionary principle note that this uncertainty is precisely why a full evaluation of alternatives must be explored.

However, the tremendous economic and military advantages offered to businesses and governments that pursue nanotechnology make it unlikely that relinquishment could ever be a realistic option. And past experiences in the international community give little hope for such a policy to be adopted. Lin-Easton notes that:

The United States ... has shown little support for the inclusion of the precautionary principle in international agreements and has resisted binding targets and timetables for the reduction of greenhouse gasses. [T]he United States has recognized the importance of nanotechnology to its economic and military competitiveness and is no more likely to support bans on nanotechnology development than it is to support reductions on its carbon emissions. (Lin-Easton 2001, p. 125)

Some scientists even note that the adoption of relinquishment would be unethical. They argue that we have a "historical imperative" to move beyond our current limitations and to acquire new knowledge. And because of the tremendous opportunities available through this new technology, turning our backs on nanotechnology would be akin to "turning our backs on the poor and suffering" (*ibid.*, p. 126).

Lin-Easton notes that given the economic and military advantages afforded to those that do fund research in this new area, it is unlikely that any government will adopt this strict precautionary principle. With that in mind, Lin-Easton outlines some anticipatory moves that can be made.

2.3 The Duty of Those Involved

To this point, Lin-Easton notes, it has been the scientists who have called for regulatory standards to be established. These proposals usually recommend the unabated research of "safe" nanotechnology while buying time to implement safeguards against more destructive forms of these technologies. Many of these proposals stem from the guidelines established by the Foresight Institute, an organization founded and chaired by Eric Drexler to educate and prepare society for "anticipated advanced technologies" (quoted in Lin-Easton 2001, p. 127). Lin-Easton summarizes the Foresight Institute's regulatory approach as "protective in development and liberal in production" (*ibid.*, p. 128).

The approach of the Foresight Institute is an attempt at self-regulation, and replaces the precautionary principle with risk assessment. This move, according to Lin-Easton, is an attempt to follow "sound science" in decision making. However, this approach relies on the ability of scientists to model complex human and environmental conditions accurately and to make predictions based on those models. Opponents of this approach note: 1) that it is precisely this sort of uncertainty in modeling that the precautionary principle attempts to overcome; 2) that it refers to acceptable risk instead of relinquishment in the face of dangerous activities; 3) that risk assessment is not democratic; and 4) that the use of costbenefit analysis creates a false dichotomy between economic development and environmental protection (*ibid.*, p. 129).

Despite these philosophical differences, Lin-Easton writes that at least three design principles and guidelines have been generally agreed upon. The first constrains autonomous self-replication. Attempts to develop safeguards to this end include the proposed use of broadcast transmissions for replication, and refusing to design any nanotechnology that would use an abundant natural resource for fuel. Second, most agree that new nanotechnologies should lack evolutionary capabilities, including artificial evolution and sexual inheritance mechanisms. Finally, guidelines should be established to prevent data corruption. This includes ensuring that if any part of the nanosystem fails, the whole device fails (*ibid*., p. 130).

Many of these guidelines have been criticized for being naïve and placing too much trust in an "honor system" amongst scientists (*ibid.*, p. 131). And environmentalists will quickly note that risk assessment often fails in its efforts to prevent human or ecological damage (*ibid.*, p. 132). To combat this, Lin-Easton argues that "much wider participation in these discussions is needed to tighten the proposed guidelines and to address the necessary regulatory mechanisms that will be required to implement them" (*ibid.*, p. 132).

2.4 Creating a Forum for Discussion

As mentioned above, much of the discussion about regulation has come from within the nanotechnology community. However, because nanotechnologies are poised to have such broad effects, many like Lin-Easton are calling for an open discussion of these new technologies. To accomplish this, the public need to be made aware of recent developments, and must be afforded the opportunity to participate in discussions concerning the research, development, and manufacturing of new nanotechnologies. Lin-Easton describes the relevance of the Rio Declaration to this situation: "The Rio Declaration calls for the discussion of environmental issues to include the 'participation of all concerned citizens' and for states to 'facilitate and encourage public awareness and participation by making information widely available'" (*ibid.*, p. 133).

Lin-Easton closes by saying that dialogue needs to begin now. And while the nanotechnology community may resist some demands, the early involvement of the public may prevent over-reaction in the future. "The resulting debate is likely to be contentious, but dialog needs to start now, so that proactive precautionary social and legal controls can be developed while this new technology is still in its early development, rather than rushing to rash reactive policies in response to a rude awakening thirty to fifty years from now, if not sooner" (*ibid.*, p. 134).

3. Creating a Space for a More Democratic Discourse

The fact that nanotechnologies should be regulated sooner rather than later is clearly evident from the work of Fiedler and Reynolds and Lin-Easton. The question is not "if", but "how" regulation should be implemented. To this end, these authors have called for further involvement on the part of their respective communities – lawyers, environmentalists, doctors, and scientists. But, given the possible ramifications of the development for these new technologies – socially, economically, politically, environmentally – I want to argue for the involvement of an even broader spectrum of voices to be heard in these discussions. The key to this, as Lin-Easton points out, is the education of the various publics and the opening of a forum that includes them. Therefore, I would like to close with a discussion of a few topics that will be important for claiming this space for debate and empowering those involved, that is, restoring a sense of agency to them.

3.1 Re-Defining Social-Technological Relations

Technology does not impact society. This is the impression that we are given when we look at discussions of how society must prepare for the coming of nanotechnologies. Very little, if any, attention is given to the role that society plays in shaping, choosing, designing, and reinventing technologies, both before they are 'closed' and after they have been in use for years. The role of the social in the design and implementation of technologies has been thoroughly explored, from the introduction of the bicycle to the creation of tactical aircraft.¹ Rather than accept this model of society as inheritor or society as impacted by technology, we ought to stress the ways in which technology and society are inextricably linked, and how we are as much the creators of technologies as technologies are the creators of our societies. The ways in which societies decide to develop and manufacture nanotechnologies will be a reflection of who they are. Concurrently, these new technologies will recreate our society as they begin to offer new hopes in medical treatments and environmental cleanup, and new dangers – both accidental and intentional. Thus, focus should not be exclusively on preparing society for nanotechnologies, but equally on deciding what kinds of nanotechnologies societies want to create.

3.2 Technological Determinism

The development of technology does not proceed down a predetermined linear path from point (a) to point (b) with nothing to stand in its way. That is, there is no technological determinism. And while this topic has been dealt with extensively over the past few decades in the history of technology and less so in the philosophy of technology, there are still those – including many policy makers – who assume that this is the way things work. In order to create an educated and empowered public capable of participating in the development of nanotechnologies, the myth of technological determinism must be cast away. It may be true that technologies gather a sort of momentum – as the historian Tom Hughes has argued – the further along the technology develops.² After all, that is the reason why the authors I have discussed here are pushing for early regulatory action. But, we must remember that we are never powerless. Moves made in the past may constrain our moves in the present, but they certainly do not determine our future. And while ideas like relinquishment may seem unlikely, they should not be treated as impossible.

The issue of technological determinism is surely not only a concern in the public sector. The idea that – like it or not – we are subject to the continuous development of technology is a popular one in all sectors of society, including the professional groups working on the development of nanotechnologies. Groups such as the Foresight Institute take as their base assumption that these technologies *will* be developed – it is only a question of *when* and by *whom*. As Lin-Easton points out above, relinquishment is never considered as an option. Instead, we, the public, are given the impression that nanotechnologies *will* be developed and produced and that we need to prepare ourselves as best as possible for this in the near future. But, *who* should be preparing us?

3.3 Overcoming Expertise

According to Fiedler, Reynolds, and Lin-Easton, the legal world ought to be doing more to prepare for new developments in nanotechnologies. But scholars such as Sheila Jasanoff point out that the courts are usually ill-equipped to deal with new or changing technologies (Jasanoff 1995, especially chapter 3). This leaves a heavy burden on the courts and legislators to find reliable experts. Despite numerous attempts to deal with issues of expertise in the courts,³ there remains little consensus on how to regulate expertise itself. This particular landscape often creates an environment where scientists are left to regulate themselves by playing the dual role of concerned citizen and regulatory advisor. Take for example the work of the Foresight Institute. Learning lessons from the trouble encountered by genetic engineers in the 1990s, those working at the Foresight Institute have attempted to move preemptively to clear the path for emerging technologies, such as nanotechnologies. The institute is a site for educating the public, providing information to lawmakers, and for debunking perceived popular misconceptions about the potential dangers that could accom-

pany this new class of technologies.⁴ To be sure, organizations such as the Foresight Institute express the seemingly good intention to educate the public about their vision of emerging nanotechnologies and – in the words of their mission statement – to "help prepare society for anticipated advanced technologies", But despite these intentions, there is a noticeable lack of attention given to *involving* the public in this discourse. The work of the Foresight Institute (and similar institutions) thus runs into the same problems encountered by those who formulated the "Public Understanding of Science" movement in the UK. As part of that movement, questions arose around issues such as: who would be doing the educating, what information would be disseminated, and how? But, more importantly, concerns were raised about the overtly paternalistic approach of the movement and the homogenization of 'the public' into a single group that needed to be educated. Critics argued that efforts should be made to engage the various publics and to make them active participants in the *debate*, not passive and docile recipients of advanced sciences and technologies.

Is there a way around this ad hoc creation of expertise? Is there a way to educate the publics without removing their ability to actively engage in critical debate? As Lin-Easton remarks above, there is not only a desire but also a need to involve a broader public in the debates concerning new and emerging nanotechnologies, and the "Wingspread Statement on the Precautionary Principle" is certainly one place to begin. But does this address the entire problem? Rather than rely exclusively on articles such as the Precautionary Principle, we ought to be working to create a more inclusive, democratic approach to these new technologies.

3.4 The Creation of a Democratic Technology

New technologies should serve the needs of our entire society, not specific interest groups. And because the greatest risk from new technologies often falls upon those least likely to benefit, every effort should be made to create an open and democratic approach to the regulation of new nanotechnologies. This is the message of the "Wingspread Statement on the Precautionary Principle" that is echoed by Lin-Easton. But how does one go about creating a democratic technology? Well, there are several ways. Certainly the calls by Fiedler, Reynolds, and Lin-Easton are legitimate. They ask for the involvement of lawyers, environmentalists and others to become involved in the project of regulation. Clearly, this is an important means of intervention. However, as the philosopher Andrew Feenberg points out, working within the traditional structures of democracy is only one option (Feenberg 1999, pp. 105-6). He offers three other modes of intervention for including citizens from multiple walks of life. First is the creation of technical controversies. "Controversies draw attention to violations of the rights and health of those affected by the enterprise" (*ibid.*, p. 122). The result can often be the exposure of the complexity of the elements threatening health and environment – in this case nanotechnologies – and the ideological views that previously characterized the technologies. The second mode of intervention is innovative dialogue. These dialogues often occur when intellectuals from the "inside" – engineers and scientists involved in the creation of nanotechnologies – actively engage the public. The active engagement with local participants can lead to two possible outcomes: 1) the dialogues are marginalized and suppressed by those with greater resources, or 2) what is learned in these dialogues is internalized and becomes a part of the new technologies (*ibid.*, pp. 123-4). The third mode of intervention proposed by Feenberg is creative appropriation. This approach involves the "interpretive flexibility" of a technology, that is, the ability to rethink, reinvent, or transform the technology through new uses – and concurrently the society that uses it: "At issue in this transformation is not just the [technology's] narrowly conceived technical function, but the very nature of the advanced society it makes possible" (*ibid.*, p. 127).

In the end, we must remember that it is we – society writ large – who will decide what nanotechnologies will be and how they will mesh with our society. We must not for-

get that it is never too late, or too early, to rethink the types of technologies we want our society to create, and how we want these technologies to alter our societies. I close with a final quote from Feenberg: "Even as technology expands its reach, the networks are themselves exposed to transformation by the individuals they enroll. Human beings still represent the unrealized potential of their technologies. Their tactical resistances to established designs can impose new values on technical institutions and create a new type of modern society" (*ibid.*, p. 128). It's never too late to begin including new voices, new ideas, and new goals in the designs and implementations of our society's technologies.

Notes

- ¹ For the debates surrounding the design of bicycles, see for example Pinch and Bijker 1987. For discussion of the British TSR2 Tactical Strike Fighter, see John Law 2002.
- ² See, specifically, Hughes 1987. The concept also receives some attention in Hughes 1983.
- ³ Specifically, the cases of *Daubert, Khumo Tire*, and *Joiner* have dealt with the issue of expertise in the courts. For some analysis of how the *Daubert* case has functioned, see Jasanoff 1995, especially chapter 3. For a more recent discussion, see Berger 2000.
- ⁴ As an example of the debunking efforts of the Foresight Institute, look at the Press Releases that followed the publication of Michael Crichton's book *Prey*, found on its website www.foresight.org.

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