The revolution in nanotechnology has brought with it a nanotechnological way of seeing the world.1 By opening the “black box” of nanotechnology, scientists have changed the way we envision future developments in medicine, manufacturing, computing, and robotics, to name a few examples. However, much of the public, including physicians, are poorly prepared for this revolution, and require a new way of understanding these advances, assessing risks and benefits, and appreciating the potential impacts of nanomedicine on healthcare. In the field of nanomedicine, these issues will become particularly relevant due to the increasing politicisation of the nanotechnology debate, and subsequent calls for new regulations by non-governmental organisations and other concerned actors.2 In short, the future of nanomedicine depends on the degree to which nanotechnology as a whole garners wide-scale public support.

At this point in time, the risks and benefits associated with developments in nanomedicine are largely hypothetical and illustrative of larger questions that accompany new technological developments. Early developments in nuclear medicine and biotechnology provide us with lessons for assessing the likely impact of nanotechnology on medicine. The development of nuclear technology for military purposes during World War II changed dramatically the tone of the 20th Century.3 Not only did the deployment of nuclear weapons by the United States of America end the war, but it ushered in a new era of international competition in the form of an arms race. Civilian applications of nuclear technology were developed in the 1950s and 1960s with the advent of nuclear reactors for electricity production, and with the development of radioisotopes and refinements in medical imaging technology. Although nuclear reactor developments have stalled in many parts of the world, the medical applications that came from an improved understanding of the atom occupy an important role in the history of medicine, and have generally been well-accepted by patients. This acceptance of nuclear medicine by patients, and physicians alike, has come about primarily due to the demonstrable benefits of this technology, and from a growing general acceptance of other technologies that expose us to different kinds of electromagnetic radiation (e.g., microwave ovens, cellular telephones, wireless internet).

In the case of biotechnology, the story is somewhat different. Biotechnology has followed a more turbulent path. There are two main reasons why biotechnology has failed to capture wide-scale public support.4 First, the benefit-to-risk ratio from innovations in agricultural biotechnology is poorly balanced for consumers. Consumers of genetically modified food have been offered food with traits that confer primarily herbicide-tolerance and insecticidal properties. Consequently, it should be of little surprise that consumers resist food that provides little direct benefit, and some level of risk (even if theoretical). Second, the public, especially in European countries where BSE (mad cow disease) became a public relations problem, continues to show a decline in trust in science and in governmental regulation. Trust is difficult to build and easy to lose. The development of innovations in biotechnology has been hampered by this lack of trust due to public concerns about the adequacy of the regulatory process, its openness and
transparency, and potential conflicts of interest arising from government, industry and university partnerships.

To avoid some of these pitfalls, developers and advocates of nanomedicine need to consider the following observations. A serious mistake made by many proponents of biotechnology was a failure to consider risk and benefit simultaneously. This mistake is especially prominent amongst industrial actors who hyped the benefits of the biotechnology revolution without paying much heed to potential risks. By ignoring or downplaying the risks, and touting the benefits of a technology, much is jeopardized. On one level, this strategy creates a risk information vacuum that can be colonized very effectively by non-governmental organizations like Greenpeace, Friends of the Earth, and other actors. Since messages about risk sell more easily than messages of benefit in the court of public opinion and in the media, this strategy is ill advised. With respect to nanomedicine, physicians need to be sensitive to this issue since patients continue to become more sensitised to risk and benefit due to the greater availability of information from competing sources like the Internet. On another level, by not openly discussing risks and benefits together, trust is difficult to re-build. Low levels of trust make technologies inherently unstable from a social perspective, and often lead to overreaction. For example, the civilian nuclear industry lost considerable amounts of public support following a minor accident at Three Mile Island and a more serious accident at Chernobyl. Although these accidents did little to affect public support for nuclear medicine, in this current climate of weak trust in institutions of science and government, an accident resulting from a product of nanotechnology could potentially harm the prospects of nanomedicine. By working to actively build trust by discussing risks and benefits, this potential is weakened.

When transformative technologies like information technology, biotechnology and nanotechnology enter the public sphere, two kinds of general regulatory questions usually arise. First, are these technologies significantly different from earlier technologies? Second, what is the appropriate balance between regulating a technology early and aggressively to protect human health and the environment, or phasing in such regulation slowly to stimulate innovation? At the moment, no nano-dedicated regulators exist anywhere in the world. The absence of specific regulations for products of nanotechnology sends a powerful signal to developers of this technology to continue with the production of intellectual property. Unfortunately, the absence of specific regulations for nanotechnology, and by proxy for nanomedicine, creates some contradictions. One critical contradiction comes from the issue of novelty. If the products of nanotechnology are no different than other technologies, just at a smaller scale, why is there development so worthy of pursuit? Another contradiction arises from the issue of convergence. In the same way that regulators of telecommunications have had to deal with the convergence of the Internet with television and radio broadcasting, file sharing, and cellular telephones that have multiple functions (e.g., onboard digital cameras, Internet access), regulators will soon have to face the fact that nanotechnology is converging with biotechnology, and other domains. Nanotechnology will undoubtedly raise several social and ethical issues that go beyond the mandate, and core competencies, of regulatory bodies that have traditionally dealt with agricultural, medical, and environmental issues in isolation (and who have traditionally defined social and ethical issues as non-regulatory). For nanomedicine, the coming of this regulatory watershed could mean considerable confusion about whether innovations are regulated ultimately as drugs, devices, or hybrids of the two.

As the frontiers of nanomedicine become increasingly delineated and begin the inevitable process of replacing “traditional” approaches to medicine, several other kinds of questions are likely to emerge. First, how will these new technologies get diffused through the system? The incremental nature of these developments is likely to parallel, at least initially, the clinical trials model. New drugs, devices and hybrids will have to prove equivalency, or superiority, to the “gold standard” treatment that currently exists. Some advances in nanomedicine are likely to usher in significant changes in healthcare delivery that may potentially amplify existing social problems. For instance, will expensive new therapies exacerbate the already wide gulf between the rich

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and poor in terms of access to medical treatment by creating a nano-medical divide? Can countries that have universal health care systems in place afford to partake in this medical revolution, or must the stated goal of universal accessibility be jettisoned? Can some advances in nanomedicine, like the development of microfluidic platforms for genetic testing, create threats to individual privacy if adopted for non-clinical applications by insurance companies and employers? In closing, the future of nanomedicine is dependent on several social, regulatory and clinical issues that need exploration sooner rather than later. If nanomedicine is to grow into a cost-effective, socially acceptable, and valuable field in medicine, it is important for physicians and others to recognize that its success, or failure, is contingent on the degree of support it receives from the public. This support can be nurtured by a thorough discussion of the risks and benefits, by encouraging the development of an appropriately constituted regulatory system that can deal with issues like convergence and novelty, and by fostering an environment that seeks public input early and often.

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