Government Office for Science

INNOVATION: MANAGING RISK, NOT AVOIDING IT

Annual Report of the Government Chief Scientific Adviser 2014

INNOVATION: MANAGING RISK, NOT AVOIDING IT

This is the first Annual Report of the Government Chief Scientific Adviser, Professor Sir Mark Walport.

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This report is intended for:
Policy-makers, legislators, and a wide range of business people, professionals, researchers and other individuals whose interests relate to the link between risk and innovation.

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The report project team was David Bennett, Graeme Collinson, Mike Edbury, Elizabeth Surkovic and Jack Wardle.

The purpose of this report

As this report is published, Ebola is raging in West Africa. Already-weakened economies are struggling. Scientists, pharmaceutical companies and regulators are working flat out to develop new treatments and new vaccines. No one would dispute the vital need for innovation to control and reduce the risks from this terrible infection. Once again, we are reminded that the forces of nature hold many of the trump cards in the evolutionary relationships between humans and other species on the planet.

This epidemic serves as a reminder of the things that governments really care about. These can be distilled as the health, wellbeing, resilience and security of citizens, underpinned by a strong economy. All of these depend on our social, physical and natural infrastructures. Societies crumble very quickly if they are disrupted. Science has much to tell us about infrastructure and that is why scientific advice to governments is so important.

The infrastructure created by humans and the natural infrastructure of the planet are both vital for our survival and wellbeing. It is only possible for more than seven billion people to inhabit the Earth because of our ability to modify our environment. We achieved this by creating social and physical structures, and by discovering how to harness the fossil energy sources of the planet to power our modern world. But in spite of all our innovation and ingenuity we are still critically dependent on our natural infrastructure, on our interactions with animal and plant health, on weather, climate and all the other aspects of the physical and biological environment of the planet.

At the same time as we were learning how to modify our physical environment to improve our living conditions, we were building social and economic structures. We are as dependent on these as on our built environment. Modern economies were developed through politics, trade and specialization, shaped from time to time by war and conflict. The Industrial Revolution of the eighteenth and nineteenth centuries started in Great Britain, and we are now going through a second equally tumultuous revolution — the Information Technology Revolution — which is likely to play a similarly important role in the development of societies and economies of the future.

The topic of this report is innovation and risk. Why have we chosen this topic and how have we gone about our work to reach our conclusions? Firstly, innovation is essential for economic growth, health, wellbeing, security and resilience. In Chapter 1 of the companion volume "Innovation: Managing Risk, Not Avoiding It. Evidence and Case Studies", Nick Stern and his colleagues describe how many of the greatest periods of economic growth in the past have been driven by innovation. The need to innovate is a fundamental requirement for social and economic progress. Innovative economies are more competitive, respond better to change, see higher returns on investment and create increased living standards. Innovative businesses are more productive and grow faster than businesses that fail to innovate. And it is not only businesses that must innovate: governments and social organizations need to innovate to adapt, respond to and shape the evolution of society. Governments have an essential role in shaping the legal frameworks, institutions and policies that in turn shape the risks and incentives faced by others. It is this balance of risks and incentives that determine what choices innovators, entrepreneurs, investors, inventors, bureaucrats and citizens will make.

Secondly, we need innovation just as much today as we did at the time of the first Industrial Revolution, even if the reasons are slightly different. The innovators of the eighteenth and nineteenth centuries in Great Britain were motivated by and working against a backdrop of widespread poverty, high child-mortality and extremes of crime and squalor. This is no longer the case — at least in the United Kingdom.

In Chapter 2, Ian Goldin describes the background against which innovators are operating in the twenty-first century: global population growth, continuing climate and environmental change and large socio-economic shifts. Other significant trends include continuing increases in available data, computing power and bandwidth; and a greater likelihood of scarcity in natural resources, including oil and water, phosphates and rare-earth elements. Innovation is needed in the future to develop better ways of producing and disposing of goods, and for delivering services.

However, innovation is not an unalloyed good — almost all innovations can cause both benefit and harm. Because of this, discussion of innovation has become almost inseparable from discussion of risk. Paradoxically, this discussion has become more prominent precisely because the innovations of previous generations have made our lives much safer and free of risk. People living in advanced economies have become more risk averse compared to previous generations.

A common denominator of innovation in every generation is that it solves problems, creates wealth and new employment, while at the same time potentially disrupting the status quo of existing wealth and employment, and creating new problems and challenges.

The Industrial Revolution began in the absence of much legislation or regulation. However, it is a mistake to think that innovation was not strongly contested then, for reasons that were similar to those we see today: the vested interests of those profiting from incumbent technologies; clashes of values or religion; or protests by those whose lives were disrupted or disturbed by change. Societies, then as now, responded to the challenges posed by innovation and to their adverse consequences — railway and road fatalities, for example — with a mixture of legislation and regulation.

This brings us to the present time and to the third reason for this report. The task of designing systems of regulation and practice that are based on rigorous evidence and well-informed public debate is difficult. In some areas, regulatory systems have become sclerotic and stifle growth. In others, ambiguity about 'who is accountable for what' acts as an inhibitor. Debates about risk are often highly technical while, at the same time, being at least as much about values and choices, about who benefits and who pays. Social, political and geographical contexts matter hugely, and this is especially true when seeking to establish frameworks across national boundaries. When governance goes wrong, we can miss out on major potential benefits, or suffer needlessly.

This report builds on recent creative thinking about innovation, benefit and risk, drawing on experience and observation. The authors of this report have brought together perspectives from a wide range of disciplines. Our aim is to help policymakers and citizens to make better-informed choices about innovation. In order to do that, we focus on the ways in which risk can be governed most effectively. We invite debate about how the principles outlined in this report should be applied to decisions taken at local, national, European and global scales.

We are enormously grateful to the experts who wrote the chapters and case studies of the companion report. In addition, many of them helped to shape the report through discussions and meetings. Discussions of risk and decision-making can seem rather abstract; so the chapters are complemented by case studies — on topics from genetically modified (GM) crops to the regulation of financial services — that illustrate how the outcomes of decisions about risk have very direct effects. The chapters and case studies represent the authors' personal views rather than those of the Government Office for Science, but the chapters provide the evidence base for the Government Chief Scientific Adviser's calls for action. This report is our response to that evidence base, and is aimed at policymakers and regulators.

Innovation, risk and government

Chief Scientific Advisers to the UK government learn quickly that a key and largely unsung role of the government is the difficult job of managing the risks facing the UK population. The performance and resilience of our infrastructure is at the root of many of these risks. The United Kingdom has a well-developed public facing National Risk Register, based on a classified National Risk Assessment. This assesses the likelihood and potential impact of civil emergency risks — but one of the hardest decisions for the government is to find the right balance of both effort and expenditure in preventing and mitigating the consequences of individual risks and, in the event that they transpire, managing and clearing up the consequences. How much money should be spent on flood defences, on vaccines, on hardening our telecommunications and energy infrastructure against the effects of strong solar flares? The list is long. Indeed, it is almost a no-win game — there is flak from the public, media and opposition politicians when things go wrong, but little or no recognition when adversity is averted.

And sometimes we fail to recognize that the extremes of the physical and biological systems that shape the environment will ultimately beat all but the most resistant human infrastructure, whether those are extremes of rain, wind, geological forces or infectious diseases. When more than one metre of rain fell on South West England at the end of 2013 and start of 2014, it was inevitable that flooding would be the consequence, particularly in flood plains such as the Somerset Levels.

The threat of extreme rainfall is rising as the climate of the planet changes, so tough decisions will have to be made about how much to spend on things such as flood defences. And

> **Innovation is essential for economic growth, health, wellbeing, security and resilience.**

when rivers meet the sea and tides, the difficulties and costs of defending against extreme weather become extraordinarily challenging and costly. How much and where to spend are decisions for politicians and society — the role of science advisers is to describe, analyse and explain the hazards, risks, threats and vulnerabilities. One thing is for sure: innovation is essential if we are effectively and cost-effectively to future-proof our national infrastructure to provide the best and most affordable security and resilience to UK citizens.

The United Kingdom starts in a very strong, indeed world-leading, position in the assessment and management of the risks facing our population. It is one of the few countries in the world to have a publicly available National Risk Register, with a strong and deeply embedded civil contingencies secretariat and well-rehearsed disaster prevention and management protocols and procedures. Following the United Nations' (UN) World Conference on Disaster Reduction in Kobe, Hyogo, Japan, in 2005, the Hyogo Framework for Action was developed with five specific actions:

1. Making disaster risk reduction a priority.
2. Improving risk information and early warning.
3. Building a culture of safety and resilience.
4. Reducing the risks in key sectors.
5. Strengthening preparedness for response.

The United Kingdom has been audited against these actions and strongly commended for its work. It should continue to develop the role for innovation, evidence and risk evaluation in delivery of resilient infrastructure. To achieve this the UK will need further to develop the National Risk Register as a key part of the discussion and debate inside and outside the government on the priorities for action on national infrastructure and resilience investment. (This will build on the approach taken in the Hyogo Framework for Action).

How to frame discussions of risk and innovation

Innovation creates change and, for both individuals and societies, this always carries risk, with the potential for harm as well as benefit. Further, because predicting the future is extremely difficult, there is plenty of scope for uncertainty and controversy. As Andy Stirling describes in Chapter 4, the issue at stake is rarely a simple question of 'yes or no?' or even 'how fast?', but more often 'in which direction?', 'what are the alternative choices?', 'who leads, gains, and loses?' and 'why?'.

Indeed, innovation is often discussed mistakenly in generic rather than specific terms. For example, it is not sensible or meaningful to ask whether a technology such as nanotechnology is, in and of itself, a good or a bad thing. The questions are always specific. Are nanoparticles of a particular composition an appropriate way to monitor a specific environmental hazard? Or is there an unacceptable risk of inhalation of a particular nanoparticle that is released as a consequence of its use in a household product? In the case of GM organisms, the questions are: 'what gene?', 'in what organism?', and 'for what purpose?'. Almost any technology has the potential for both beneficial and harmful uses and in every case we need to work out how best to exploit the benefits while minimizing the harms.

We should be careful of the 'Pandora's box' argument, which is that a new technology may lead to an unforeseen series of consequences that may pose existential risks to the human race. Nick Beckstead and Toby Ord describe in Chapter 10 the particular challenges presented by the very narrow class of risk concerning high-impact events which are conceivable in principle, but about which we have little evidence to inform decisions. In these cases we must constantly scan the horizon to do our best to prevent and mitigate adverse consequences of new technologies. But Pandora's box was opened when the earliest humans discovered fire, and when they developed the capacity to refine and work stone and metals. The rest is history.

Acknowledging uncertainties and the breadth of opinion and debate on an issue does not inevitably lead to delay and complexity. The clear message from our authors is that we all constantly make decisions based on imperfect information, both professionally and personally. That is ultimately the only way to get things done. In making regulatory decisions, however, and in framing the ways in which decisions are taken, we can move further, faster and more robustly by observing a few key guidelines.

Firstly, each decision about the risks and benefits created by applications of a new innovation needs to be considered in the round. We usually focus on the risks of acting, but not acting is also a choice that may create its own risks. Equal attention needs to be paid to the consequences of inaction.

Secondly, robust decision-making and debate needs to take account of the different ways to achieve the same or a similar aim. And for each of these, the claims for benefit and for harm need careful analysis.

Thirdly, science is usually one lens amongst several through which we view and debate innovation and risk. It is an essential lens, but not the only one. Economic, social and political lenses may also be considered. Debates about risk are also debates about values, ethics and choices; about how benefits and risks are judged; and about fairness, or who benefits and who carries the risk. If these broader questions are ignored, conflicts can become intensive and disabling. It is important that scientists working with decision makers recognize the breadth of the discussion, and equally important for decision makers to realize that science is a vital component of that discussion. Widening the conversation is a democratic necessity and an expression of responsible citizenship.

This takes us into a discussion of the science of risk and risk communication.

Application of the science of risk and risk communication enables the best discussions

Policymakers and regulators need to be extremely clear about the factors to be considered in any rational discussion about risk. We have just considered one of these: the need to look at innovation in terms of specific possible applications, rather than in a generic fashion.

One of the biggest challenges is to distinguish between hazard, exposure, risk, and vulnerability. Understanding this terminology really matters. This is because hazard is frequently equated or confused with risk, and this leads to poor debate, confused communication and flawed decision-making.

The simplest illustration of the importance of the distinction between hazard and risk can be found in the contents of our kitchens. These are full of hazards: sharp knives, boiling kettles, exposed electric filaments in toasters, salt, bleach and other noxious chemicals. We avoid the risks of these hazards by reducing our exposure to them. So we avoid poking metal conductors into our toaster, or pouring bleach into our stews. These examples illustrate that risk is a product of the hazard and our exposure to it. Indeed a hazard with no exposure poses no risk.

The additional factor in the equation is vulnerability. Some of us are more vulnerable than others, so we are careful to separate young people from boiling kettles. We put safety lids on bleach bottles to restrict youngsters from curious sampling of the contents. The point here is that the increased vulnerability of small children is caused by their greater sensitivity to the hazard of a sharp knife or toxic chemical, and that their likelihood of exposure is higher.

Especially for novel or unfamiliar risks, we must also take account of uncertainty. This addresses the degree to which we are confident in our knowledge of hazard, exposure and vulnerability.

These examples illustrate the importance of understanding that risk is a product of hazard, exposure and vulnerability. All of these must be considered, together with the degree of certainty in each assessment, to come to a good understanding of risk. But too often we focus on one of these factors to the exclusion of others. This is illustrated to an extreme in the case of radiation: the international response of many countries to the nuclear reactor disaster at Fukushima in 2011 was a response to a deep-seated fear of radioactivity rather than a careful analysis of actual radiation exposures, which were very small outside the site of the power station itself.

In Chapter 6, David Spiegelhalter proposes some common principles for developing and ensuring the use of the best possible quantitative and rigorous science in decision-making. Science cannot be used in decision-making if it is unclear what is already known, so the first step is to review existing evidence. The United Kingdom is a world leader in the development of rigorous evidence reviews. Good examples are the Cochrane Reviews of the evidence underlying different medical practices; the reports of the learned academies, such as that by the Royal Society and Royal Academy of Engineering on hydraulic fracturing to obtain shale gas; the evidence review on bovine tuberculosis; the work of the National Institute of Health and Clinical Excellence (NICE), and the new What Works Centres. There are also good international examples of excellent practice, such as reports from the US National Academies, the InterAcademy Panel, the European Academies Scientific Advisory Council (EASAC), and those from organizations under the auspices of the UN such as the Intergovernmental Panel on Climate Change (IPCC). The common denominator of all of these is the 'meta-analysis' — a rigorous and neutral review of all of the evidence available on a particular topic.

But reviewing the evidence is just the beginning of the discussion of risk; how this evidence is communicated is equally important. We should acknowledge that any risk and uncertainty assessment is provisional and contingent. Scientific knowledge is contingent knowledge — it is dependent on the nature and reliability of existing evidence, and subject to modification and improvement by the emergence of new evidence. This is particularly the case as scientific understanding and technology evolves.

One of the challenges is how (and to what degree) uncertainty can and should be quantified. Where attempts are made to put numbers to uncertainty, the way in which numbers have been generated should be made clear. The framing of those numbers is also crucial. For example, doubling the risk of an event sounds serious, but less so when expressed as increasing a risk from one in a million to two in a million. Framing dramatically influences how numbers speak to an audience.

It follows from this discussion that a strategic, coherent and structured approach to assessing the impact of risk in policy, regulation and crisis management is essential.

a) It should be normal practice for those responsible for leading the analysis and discussion supporting innovation to be informed by independent evidence.

b) Discussions about a new technology should be founded around specific possible uses of the technology, their respective alternatives, and the costs of inaction as well as action.

c) The multi-disciplinary academic community that works on risk and risk communication in the United Kingdom is small. This community, the UK Research Councils and universities should all collaborate to fund and support the development of this capacity. The scope of the work should range from undergraduate to postgraduate courses, doctoral training and support for the next generation of leaders.

How people estimate and perceive risk

It is one thing to be able to estimate and measure risk accurately. However, objective measurements of risk may differ widely from individual and societal perceptions of risk. Over the past few years we have vastly improved our understanding of how individuals assess risk and benefit when they make decisions and take part in debates.

> **One of the biggest challenges is to distinguish between hazard, exposure, risk, and vulnerability.**

As David Halpern and Owain Service describe in Chapter 7, we know that good decision-making draws on both the analytical and the emotional systems in the brain. We know that human beings do not typically weigh up quantitative estimates of the impact of an event or outcome against its probability, even where the numbers are clear. In many cases, we make decisions instinctively. We use 'rules of thumb' based on our own experience and reinforced by our personal networks. Some of the typical consequences of this strategy are that we overestimate the likelihood of an event that can be easily recalled, for example a recent train accident; we are more concerned to avoid losses than to make equivalent gains; and we are particularly keen to avoid risks that create vivid mental pictures. But there is much more to risk assessment than our individual and collective assessments of the likelihoods of risk, which takes us to the issue of values.

When science meets values

Our individual responses to innovation and risk are shaped by our family, our friends and colleagues, and by our national identity and values. Nick Pidgeon outlines in Chapter 8 how these cultural factors influence our selection of which dangers to accept or avoid; inform views on the fairness of distribution of risk and benefit; and, crucially, influence who is blamed when things go wrong.

As a result, there are large variations in tolerance to different types of risk between countries and cultures. This means that the approach to risk and to judgments about risk may differ within and between countries. In some cases, these differences influence the way in which a country may approach and manage its whole system for considering risk and innovation. In other cases, apparently similar systems of governance evaluating similar technologies may produce different analyses of risk and different judgments.

Why are some innovations more challenging than others? We can only have the best discussion about innovations if we understand that the discussion must be about both science and values. There are some areas of technology and innovation that trigger particularly strong and immediate value-based responses, and these typically vary between different communities and countries. Obvious examples in biology and medicine are animal research, stem-cell research and reproductive technologies. In energy, almost all technologies can trigger strong emotions, whether we are considering fossil fuels, wind technologies or nuclear. In the environment, major arguments follow the consequences of the release of waste and by-products created by humans, ranging from oestrogen contraceptives excreted in urine to the excess of 10 gigatonnes of carbon emitted into the atmosphere each year by the burning of fossil fuels. In the food industry, GM organisms, pesticides, industrialized processes for agriculture and animal husbandry, and control mechanisms for animal and plant diseases, each cause strong responses in some communities and some countries.

In the case of nuclear energy, there are profound differences in the attitudes of the populations from different countries: compare, for example, France, Japan and Germany, where the historical context underlying these differences is important. Similarly, the antipathy to embryo technologies in Germany and Italy can in part be attributed to both twentieth-century history and to religious values. But one of the consequences of having a European Union of 28 nations is that almost every technology evokes immediate and strong reactions in one or more nations.

We need to be more aware of these differences, so that we can have healthier and clearer debates that make better policy at all levels. For example, there are two fundamental confusions that bedevil debate on several important regulatory topics, particularly within Europe. The first is the way in which the notions of hazard and risk are differently embedded in national modes of policymaking. This is why it is so important that we share a common understanding of the distinctions between hazard, risk, and vulnerability.

The second is a drift of interpretation of the precautionary principle from what was, in effect, a holding position pending further evidence, to what is now effectively a stop sign. To be meaningful, the precautionary principle requires a rational response to uncertainty (as distinct from risk.)

Anticipating the challenges

What are the factors that determine whether particular innovations will pose large challenges? In discussions during the development of this report, Tim O'Riordan (Chapter 5) suggested the following working model of five broad categories of innovation:

- 'Who pays?': innovations whose benefits are generally accepted, although there may be disagreement about the nature and allocation of costs. For example, some medical drugs.
- 'My pain, your gain': innovations whose wider benefits are accepted, but which impose highly local costs and impacts. For example, some forms of transport, energy or waste infrastructure.
- 'Science meets values': innovations for which the debate is largely about values. Typically this will refer to early-stage innovations and emerging science at a point when the specific applications are unclear. For example, early-stage GM technologies.
- 'Unanticipated consequences': innovations which impose unanticipated and unintended consequences. For example, many aspects of the World Wide Web.
- 'New challenges': platform innovations which are initially sufficiently governed by existing frameworks, but which may create or enable specific applications that pose new questions. For example, nanotechnologies.

The second and third of these categories appear to lead to the most heated discussions. The second applies particularly to innovations or infrastructures that have a large and localized footprint. In this case, the risks of an innovation or an infrastructure reside with one group of people and the benefits with another. This, of course, is another issue of values, concerning equity, fairness and trust. Even affected local communities are often divided according to risk and benefit at a local level, for example between those who gain employment or other amenities, and those who perceive that their lives are being threatened or disrupted in the absence of any benefit.

This is illustrated by the challenges of finding a location of a site for the geological disposal of nuclear waste. Local communities worry about the physical footprint, about how waste is delivered to the site, and about the short- and long-term safety of the radioactive material deep underground. Some will benefit from jobs and other economic externalities of the facility; others will not, and are the most likely to feel threatened and aggrieved. There is a much larger community, distant from the site, which recognizes that radioactive waste underground is safer than above ground and have none of the risks, perceived or otherwise, of the waste facility itself. This is a typical scenario for many examples of innovation associated with large pieces of infrastructure and science: economics, carefully constructed social deliberation, and politics are necessary to find solutions that are safe and fair.

The third category of innovation is when the nature of innovations and technologies clash with value systems of individuals and societies. We have already considered examples of this in the section on science and values.

Institutions and trust

We are much more likely to accept advice about new technologies and associated risks if we trust the people and institutions that develop and communicate that advice. But it is more complicated than that, because we may trust a person or institution in one context but not necessarily in another.

Judith Petts outlines in Chapter 9 how concerns about risks are often rooted in concerns about the adequacy of the institutions that produce, predict and manage them. This is likely to be particularly important for risks that are pervasive, which are not visible, and whose technological or environmental causes may only be grasped by acquiring particular types of expertise. The trusted expert or institution would typically be expected to act with care for those affected, to be competent, and to be free from self-serving bias.

Individuals and societies cannot function without trust. Transparency is necessary but not sufficient. Most of us have neither the time nor the expertise to examine every decision or explore all the evidence. We rely on judgements about the values and behaviours of those in charge. For the individual, 'critical trust' may be the best frame of mind: neither outright scepticism nor uncritical acceptance.

Who makes the decision? Effective decision-making in regulation

We delegate many decisions about innovation and risk to regulators. Regulation provides a well-tried and effective mechanism for adjudicating these decisions. In Chapter 3, Simon Pollard outlines the recent history of national risk management in the United Kingdom that has shaped existing regulatory systems and debate. Disasters such as Piper Alpha, the Herald of Free Enterprise and the King's Cross Underground fire triggered examination and action. Meanwhile, the 'better regulation' agenda has pushed towards open, transparent and deliberative analysis over many years. Pollard suggests that a variety of trends have created an increasing distinction between policymaking and regulation, with the former typically defining the core strategy in a relevant area, while the latter acts directly on the providers of technical services.

There are both generic and specific aspects of regulation. On the specific side, regulating medicinal products poses completely different challenges to regulating telecommunications. And within medicinal products, the challenges of regulating a new implanted stent to hold open a blood vessel are different to those of regulating the introduction of a new vaccine.

However, three broad generic issues in regulation stand out as particularly problematic, and each of these is related to the incentives that we provide to regulators.

The first is an unintended consequence of economic regulation. Much of our infrastructure and some of our utilities for example water are provided by monopolistic or semi-monopolistic providers. So, in the absence of a completely free market, economic regulators have been developed to protect customers. But unless the duty of the regulator includes sufficient provision for ensuring innovation and resilience, there is a danger that economic regulation will drive out innovation and reduce resilience. A 'systems approach' needs to be taken to regulation in this situation to provide the best package of incentives to the service or infrastructure provider.

The second challenge for regulation is that there are asymmetric incentives applied to many regulators. Put simply, a regulator who allows something to happen that causes harm will probably be in deep trouble. A regulator who stops something from happening that would have caused benefit will likely suffer no consequences. This is a very difficult problem to solve, because proving the counterfactual to a preventative decision by a regulator is well-nigh impossible. The best hope that we have to deal with this problem is to do our best to make regulators accountable for all decisions, both positive and negative.

The third challenge is for regulators in societies that are increasingly risk averse, where 'if something goes wrong, it is always someone's fault'. In Chapter 11, Joyce Tait describes how in many areas products have never been safer, but the regulatory processes that surround them are becoming more complex, time consuming and costly.

This can be illustrated in the world of medicine. The regulation of the development of new drugs is arguably one of the triumphs of modern medicine. But in recent years, the regulatory burden for the introduction of new drugs has increased, with parallel huge increases in the associated development costs. This may be to the detriment of the consumer, who has not been offered as many successful innovative medicines as would be expected in an era of great discoveries in medical research.

This problem cannot be placed solely at the door of the regulator. Strict product liability and the consequences of litigation mean that the pharmaceutical industry has itself become increasingly risk averse. The people who are suffering are patients with severe but relatively uncommon diseases, because the development costs of new drugs mean that there is no longer a market that can afford to pay for this innovation. This specific problem in the pharmaceutical sector has been widely recognized and is the subject of international debate. Both the industry and regulators are starting to re-examine the regulatory process, but there is much work to be done.

A 'systems approach' needs to be taken to the design of regulatory mechanisms to support innovation. Regulators need to be sufficiently agile and responsive to changes in technologies, products and services. They should have appropriate governance mechanisms, and these should ensure that the regulator may, as far as possible, be held accountable for its decisions, both to allow and to stop a regulated activity. These mechanisms should also allow regulators to file away needless rust and other encrustations on existing enforcement mechanisms.

Ultimately, a decision has to be made

Innovation is not a linear process that starts in the laboratory and ends up in the clinic, the environment or the marketplace. There is a constant iteration as new things are discovered, products developed and tried out, improved, thrown away, taken back to the laboratory, computer or factory for further iterations, until ultimately a new product may or may not emerge. Similarly, the processes that society uses to decide about the implementation of new technologies and new infrastructures, and to discuss their risks and benefits, are not linear either. This takes us to a fourth challenge for legislation and regulation: how to legislate and regulate in the face of emerging technologies and in situations where 'science meets values'.

Even where an area is complex, uncertain and highly contested, however, there are examples of very effective decision-making that rely on working with interested publics and scientists. As Lisa Jardine outlines in Chapter 12, it can be done. The model of the UK Human Fertilisation and Embryology Authority, developed to regulate the application of embryology research to reproductive technologies, is an outstanding example of regulation working alongside legislation in the face of emerging scientific understanding and competing values.

There is an important lesson to be learnt from this. It shows that a sophisticated regulator, empowered to conduct public debate as part of its work, can deliver advice over a prolonged period while both science and technology continue to evolve to enable new interventions and treatments. Because this area of science and application is in a domain loaded with values — especially deeply-held religious values — the regulator has worked alongside Parliament, which has debated the key issues and provided the underpinning legislation alongside the regulation. Although an elaborate process, it has allowed the United Kingdom to develop an approach to this difficult area of innovation and risk that is respected around the world.

However, different countries have drawn different conclusions about the acceptability of these technologies (and there have been occasional attempts to unify a European Union position in this area, which has been resisted to date).

This takes us to a further challenge. To what extent can regulation and legislation about new technologies remain nationally based, and to what extent should it be international? Arguably a simple rule of thumb is that decision-making should have an international dimension when the application of an innovation in one sovereign nation creates risks for another.

A clear example of this, looking to the future, would be the application of geoengineering technologies to mitigate the effects of global warming. Such technologies include spraying aerosols into the higher layers of the atmosphere to reduce the influx of solar energy, and adding large amounts of minerals to seas and oceans in order to capture dissolved carbon dioxide. A more contentious example is the genetic modification of crops. In this case, good husbandry can limit the spread of GM crops in the same way as for any other crop modified by traditional breeding techniques. If necessary, we might go further and use the technologies themselves to build in additional safeguards.

The challenge for the European Union lies in the diverse national perspectives on different innovative technologies. This raises the question of whether it is desirable for innovation in the European Union to proceed at the speed of the most cautious. That is a question for politicians rather than for scientists. But what the scientists should expect is that the science is seriously considered, evaluated and communicated as part of the discussion.

To achieve this the European Commission needs continually to strive to ensure rigorous scientific input. This input should inform the processes of preparing legislation in Council and Parliament. It follows that, like other regulators, European regulators should seek independent advice. They should foster and promote public discussion and debate. The outcome of that debate should inform the regulator itself, policymakers and legislators.

Meanwhile, we will work with existing EU networks to pursue further opportunities to exchange ideas and good practice on these issues at EU level, and we will bring together departmental Chief Scientific Advisers with the UK Science and Innovation Network's officers across Europe to identify priority partners for action on selected EU issues.

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