

# **GeneWatch UK's response to the Nuffield Council on Bioethics' consultation on emerging biotechnologies**

June 2011

GeneWatch UK is a not-for-profit organisation which aims to ensure that genetic science and technology is developed and used in the public interest and that people have a say about whether and how genetic technologies are used. We monitor developments in genetic technologies from a public interest, human rights, environmental protection and animal welfare perspective. Much of our work has focused on the social and ethical issues raised by GM crops and animals and human genetic databases.

This submission draws heavily on our 2010 report 'Bioscience for Life?'<sup>1</sup> and its Annex<sup>2</sup> (published online only in 2009) which describes the history of attempts under the Blair/Brown government to include the entire genome sequence of everyone in the UK population in electronic medical records in the NHS.

Not all statements below are referenced (due to lack of time) but further references are available on request or in the 'Biosciences for Life?' Report.

## **Emerging technologies**

### **1 How would you define an 'emerging technology' and an 'emerging biotechnology'? How have these terms been used by others?**

The concept of the 'bioeconomy' refers to economic activity derived from scientific and research activity focused on the commercial applications of understanding biological mechanisms and processes at the genetic and molecular levels. Emerging biotechnologies are therefore best understood as the products of the biotechnology industry, which aims to generate such economic activity. Although these technologies are often developed using public-private partnerships, using public and/or charitable funding, and are sometimes donated to end users (e.g. GM Golden Rice, if it ever achieves regulatory approval), investments are generally made with a view to generating economic growth and competitiveness, and control over markets, in a variety of areas, particularly agriculture, health and security.

### **2 Do you think that there are there features that are essential or common to emerging biotechnologies? (If so, please indicate what you think these are.)**

At a technical level, there are two main approaches to generating economic growth in the bioeconomy.

The first is based on the idea that genetic engineering is an important tool to create new products based on living organisms (including plants, animals and micro-organisms, such as bacteria). The view is of natural systems as production systems which can be modified to increase outputs, alter traits, or synthesise large quantities of biological products (such as enzymes, biopharmaceuticals or biofuels). This area of biotechnology also includes cloning and synthetic biology. These biotechnologies have common features in that they may have unintended and/or adverse impacts on other living systems, including human health, animal welfare, and the environment. These impacts are often difficult to predict due to scientific uncertainty and ignorance about complex interactions in living systems. Monopoly control over these applications is granted

through patenting, raising a common set of issues about corporate control, profiteering and the relationship between public and private interests. However, the wide variety of applications, including a variety of systems for regulation and control (e.g. contained use versus open release) leads to very different debates about different technologies and applications.

The second area of the bioeconomy is based on the idea that genetic information can also be bought and sold (including information about health, ancestry and paternity), and that human genetic information can be used as a marketing tool for other 'personalised' products, including personally tailored medicines, foods, supplement regimes or medical advice. Because DNA can be used as a biometric to identify individuals and their relatives, there are also applications in policing and security. Areas of concern relate to commercial exploitation (especially whether genetic risk predictions are reliable and useful to predict most diseases or adverse drug reactions in most people) and to issues about human rights and privacy (including both tracking and categorisation of individuals, based on their genetic make-up, and potential social consequences of this, including surveillance, discrimination and eugenics).

Whereas the economic value of genetic-engineering depends on creating and marketing new products, the value of genetic sequencing in humans depends on the interpretation of the sequence. It is therefore often the scientific and social interpretations of what the data means (e.g. for health, identity, behaviour or family relationships) that is contentious, rather than the sequencing technology itself.

An underlying feature of the biotechnology industry is a significant shift in the practice of patenting and buying and selling Intellectual Property (IP). The US biotech company Genentech's decision to enter a collaborative development and licensing agreement with Eli Lilly (to develop and produce human insulin from genetically-engineered bacteria) in 1979 is described by Gary Pisano of Harvard Business School in his 2006 book as a "*watershed event*", because it showed venture capitalists that IP could be bought and sold independently of the final product.<sup>3</sup> According to Pisano, the majority of publicly held biotech companies remain R&D firms and only 20% of them have any products on the market or are earning royalties based on products commercialised by partners. There are many more privately held firms (including many university spin-out companies) which have no marketable products. The exceptions (the only large profitable biotech companies) are the US companies Monsanto, Amgen and Genentech.

### **3 What currently emerging biotechnologies do you consider have the most important implications ethically, socially and legally?**

The main focus of GeneWatch's work is on GM crops and animals and human genetic databases. Many of these biotechnologies have been controversial for some time. However, proposals for the first commercial marketing of GM fish (in the USA) and open releases of the first GM insects (GM mosquitoes in the Cayman Islands) have put new issues on the public agenda.

GM crops raise a set of ongoing issues about corporate control over the food chain, sustainability and potential adverse health impacts. US company Monsanto controls 95% of the market in GM seeds. There is growing evidence that the two established traits on the market (herbicide tolerance and pest-resistance) are unsustainable, due to the emergence of resistant weeds and pests and new types of pest. There are concerns

that poorer farmers will become locked into a cycle of poverty if the use of such crops expands in developing countries, due to prevention of seed saving through licensing agreements, seed price hikes, and the need for increasing chemical inputs as resistance develops. Recent research (yet to be replicated) suggests that the Bt toxin may pass from pregnant women into the placenta, raising new health concerns.<sup>4</sup> Herbicide residues on herbicide tolerant crops, and aerial spraying of such crops (particularly in South America) are also a matter of concern.

Complex traits such as drought- and salt-tolerance and nitrogen-fixation have proved very difficult to deliver using genetic engineering due to the complexity of plant growth and gene-environment interactions, whilst new conventionally-bred varieties (sometimes developed using new technologies such as marker-assisted selection) have generally performed better. There is considerable investment in developing nutrient-altered GM crops, but these will pose new challenges for regulators as altered nutrient pathways can have adverse consequences on both human health and the plant itself (e.g. making it more susceptible to pests). Assessing both efficacy and safety is difficult without large scale clinical trials in target populations, which would be extremely expensive.

Open experimental field releases of GM mosquitoes produced by the UK company Oxitec have now taken place in the Cayman Islands, Malaysia and Brazil, funded by a Wellcome Trust Translational grant.<sup>5</sup> The decision to use the Cayman Islands (where there is no biosafety law) for the first release was highly controversial as was secrecy about the timing of the trials in Malaysia. Other insects, including agricultural pests such as the pink bollworm, fruit fly and olive fly, are also being genetically engineered with a view to open releases in the future and a variety of other approaches are being applied to producing GM mosquitoes. A new plan to sequence the genomes of thousands more insects may open up the prospect of multiple insect species being altered in the future, potentially changing whole ecosystems.

A genetically modified (GM) fluorescent zebra fish is being marketed as a pet in the USA, but currently there is no commercial production of GM fish as food. However, the company AquaBounty is seeking approval from the US Food and Drug Administration (FDA) to market GM Atlantic salmon in the US.<sup>6</sup> The company proposes to ship GM fish eggs from its Canadian facility to Panama, for production in an on-land facility. The fish would then be trucked to the US for sale, as well as sold in Panama. In future, AquaBounty plans to also sell eggs for production elsewhere and marketing in China. This application has been extremely controversial in the United States and may yet be blocked following a recent intervention by the House of Representatives. European salmon producers have also raised concerns because of the potential impact on wild salmon populations (a small percentage of the eggs are not sterile and very large numbers of eggs will be needed for commercial-scale production) and the expected damage to the farmed salmon market.

Britain's National DNA Database is set to be scaled back as a result of provisions in the Protection of Freedoms Bill (currently in parliament) which will destroy stored DNA samples and remove about a million innocent people's records from the database. However, a contract between the UK Forensic Science Service (FSS) to build a forensic DNA database and the entire population of UAE, negotiated by the Blair government, has yet to be cancelled (although the FSS is being wound up due to ongoing financial losses).<sup>7</sup> In other countries (e.g. South Africa) plans to copy existing UK legislation are being revisited due to concerns about cost-effectiveness as well as human rights.

Human genetic tests are still unregulated, leading to continued misleading claims about health risks being marketed directly to consumers.<sup>8</sup> The fall of the New Labour Government has led to at least a temporary respite from repeated attempts to sequence the whole genomes of babies at birth or adults using 'spare' samples collected in the NHS and store these in electronic medical records for data-mining by 'researchers'. However, there is continued lobbying by the usual suspects (the Academy of Medical Sciences, Human Genome Strategy Group, Wellcome Trust and Google) to introduce new 'data-sharing' plans continues behind the scenes, despite the spectacular failure of the last attempt (hidden in Clause 152 of the Coroners and Justice Bill in 2009).

### **Cultural, international and historical context**

#### **4 Are there examples where social, cultural and geographical factors have influenced the development of emerging biotechnologies (either in the past or currently)?**

The whole basis of R&D investment in biosciences and biotechnologies has been strongly influenced by a political commitment to building a new bioeconomy based on exploiting the discovery of DNA. This commitment began in the US in the 1980s. The vision of the bioeconomy as the basis of future economic growth (particularly as a way to boost competitiveness in comparison to emerging economies with cheaper labour costs such as India and China) was later adopted by the UK, EU and OECD.

This commitment has been reinforced by a series of powerful economic and vested interests. In the case of GM plants, the key driver has been the ability to patent GM seeds, to protect R&D investments and at the same time gain monopoly control over food markets (particularly in the major commodity crops). In the case of human genetics a long string of vested interests (beginning with the tobacco industry in the 1950s) have promoted the idea that individuals are born genetically predisposed to develop common (not just rare genetic) diseases and that these predispositions, once discovered, will be treatable. The dual purpose was to shift scientific and public attention from *external* to *internal* causes (thus protecting the markets of e.g. the tobacco, nuclear and food industries) and to expand the market for drugs and other health products (sold to healthy people to treat the genetic predispositions presumed to be inside them).

Significant investments in biotechnologies as a supposed new source of competitiveness and growth can be traced back to two reports by the US Office of Technology Assessment (OTA): in 1981 (covering the genetic engineering of micro-organisms, plants and animals<sup>9</sup>) and 1986 (covering human genetic sequencing<sup>10</sup>).

Members of the Advisory Panel for the latter report included Alfred Knudson, a member of the Council for Tobacco Research's Scientific Advisory Board. Knudson played an important role in endorsing misleading claims by tobacco-funded scientists that genetic sequencing would allow scientists to predict which smokers would get lung cancer (the intention being to promote the idea that nine out of ten smokers – those that were not genetically susceptible – could 'smoke with impunity').<sup>11</sup> In the UK, secret meetings between the (later Nobel Prizewinner) Sydney Brenner at the UK Medical Research Council (MRC) and British American Tobacco (BAT) led to the establishment of a research institute (the first pharmacogenetics institute in Europe) and journal (Pharmacogenetics) which published and promoted false claims to have found genes for lung cancer, and to Brenner securing support for human genome sequencing from

Margaret Thatcher.<sup>12</sup> The entire field of behavioural genetics also rests on false claims made by tobacco-funded scientists about the role of genes in 'smoking behaviour'.<sup>13</sup> The idea (which originated with the eugenicist Ronald Fisher, who worked as a consultant to the tobacco industry in the 1950s) was that the statistical link between smoking and lung cancer could be explained as a 'genetic coincidence' if the same genetic factors caused people to smoke as well as to be more susceptible to cancer.

A long string of other vested interests later adopted these ideas in order to promote the concept of genetic 'prediction and prevention' of disease, including the food industry (which copied the tobacco industry's approach and applied it to hypertension, diabetes and obesity), the nuclear industry (which set up the first biobank in Europe near Sellafield<sup>14</sup>) and the pharmaceutical industry (which hoped to massively expand the drug market to healthy people).<sup>15</sup> More recently, Google has sought to capture genetic data as a step to 'personalised marketing' using the company 23andMe, funded by Google and run by Google-founder Sergei Brin's wife.<sup>16</sup>

The OTA report on genetic engineering followed the 1980 ruling of the US Supreme Court, in the landmark case of *Diamond v. Chakrabarty*, that genetically engineered micro-organisms are patentable. This decision, and the international agreements that followed, drove corporate investment in biotechnology (including both genetic engineering and human genome sequencing), and science policies on both sides of the Atlantic that sought to invest in and promote a new 'knowledge-based bio-economy' (KBBE).

### **5 Are there examples where social, cultural and geographical factors have influenced public acceptance or rejection of emerging biotechnologies?**

The 1999 Genome Valley report identified a need for changes in school curricula to encourage young people to study biological sciences and to make them "*informed consumers*"; and provision of modern biological research equipment into schools and especially into Universities to prepare the generation who will "*reap the benefits of the biotechnology revolution*".

However, this attempt to create "informed consumers" (presumed to be convinced of the benefits of eating GM crops or having their genome sequenced) has not been entirely successful at creating widespread acceptance of all biotechnologies: most notably in the case of GM foods. In addition, few consumers have been persuaded to buy genetic tests marketed direct-to-consumer (the market leader 23andMe has sold only 100,000 tests, mainly in the USA<sup>17</sup>, despite appearing on the front page of Time magazine and on the Oprah Winfrey show) and most medical professionals remain adamantly opposed to widespread genetic screening unless evidence shows it improves health outcomes (which will only be the case in rather restricted circumstances).

One cultural difference between Britain and the USA is that the message that people have a right to access their own DNA (in reality, a commercial interpretation of it) appears to have (slightly) greater purchase in the USA. In Britain, people tend to trust the expertise of doctors and are probably more likely to distrust health claims made by commercial companies.

## **6 Are there examples where internationalisation or globalisation of research, markets and regulation have influenced the development of emerging biotechnologies?**

The most important area of internationalisation has been the intellectual property (IP) regime, which has been exported (with various modifications) from the US via lobbying and international agreements.

The model of innovation that underpins the idea of the bioeconomy has also been widely exported from the US to other countries. Scientific institutions are routinely set up in countries such as Pakistan and Bangladesh to lobby for introduction of GM crops and develop biosafety laws (a requirement of the Cartagena Protocol). The Wellcome Trust has created an initiative to establish and link biobanks across the EU and helped set up biobanks in Africa and China. Mexico's biobank is supported by Nestlé (which wants research on the rapid rise in diabetes and obesity to focus on genetics, not on its products).

Internationalisation of the market has frequently been used as a spurious argument against regulation of genetic tests and to argue that the public must accept the import of GM crops into the EU. These claims rely on making people feeling powerless to change events, rather than on convincing them of benefits.

## **7 How have political traditions (such as liberal democracy) and political conditions (e.g. war) influenced the emergence of biotechnologies?**

The concept of scientific and economic progress embodied in (some interpretations of) the industrial revolution has frequently been used to support emerging biotechnologies. Critics are labeled 'Luddites'.

The loss of autonomy associated with many biotechnologies (see below) tends to be portrayed as inevitable by advocates (GM crops will be everywhere in the food chain, or every baby will have its genome sequenced at birth), or as necessary to capture significant predicted benefits (e.g. an end to cancer, feeding the world). Rejecting these technologies, or using them only in more tightly defined circumstances is portrayed as "anti-science", "anti-technology" or "anti-progress" and as leading to unacceptable and even devastating consequences (e.g. babies will die, murderers and rapists will walk free). The idea that people should have a choice about what research is done and which technologies are implemented is seen as a fundamental threat to the very idea of scientific progress.

During the New Labour government, the idea of biotechnology as a key driver of the future economy was entrenched through the role of the 'biotech barons': the major funders of the Labour Party without which New Labour would have been unable to exist. Both science ministers (Lord Sainsbury and Lord Drayson) were members of this small circle of individuals who promoted exaggerated promises about the future role of bioeconomy. Neither was elected, both had significant investments in biotech companies, and both benefited from R&D tax credits and other measures introduced as a result of their own policies.

## **Ethical, policy and public engagement issues**

### ***General***

**8 Are there ethical or policy issues that are common to most or many emerging biotechnologies? Are there ethical or policy issues that are specific to emerging biotechnologies? Which of these, if any, are the most important?**

Many biotechnologies may be regarded as ‘technologies of control’, which have negative effects on autonomy due to a combination of technical and economic factors. In general, the concept that science “adds value” to goods and services in the ‘knowledge-based economy’ (of which the ‘knowledge-based bioeconomy’ (KBBE) is a central part) tends to create a tension with consumers, who are dependent on scientists to tell them which of these new products are really good for them.

This is most obvious in the case of GM foods. Where in the past rice was rice and a tomato a tomato, health concerns were usually identifiable through human experience and immediate senses (sight, smell, taste), putting the onus on individuals and families to know where their food came from and whether it was safe and good to eat. The ability to engineer substantive changes into foods (e.g. pesticides in Bt brinjal, human milk proteins into cow’s milk or rice) now makes people dependent on the regulatory system. Because GM crops may contain harmful or potentially harmful substances (including toxins, allergens, pharmaceuticals, industrial chemicals or altered levels of nutrients) consumers are dependent on regulatory regimes to guarantee safety, segregation, choice and an ability to recall products should anything go wrong. Companies then require regulators to defend their claims of both benefits (e.g. ‘health claims’ for biofortified foods) and safety, but at the same time regard the regulatory system as a burden, adding significantly to costs, and continually attempt to undermine it.

These issues are not unique to GM foods but reflect wider patterns of change in the food chain (where many people no longer know what is in the processed foods they eat and where food pathogens can spread rapidly through long industrialised food chains). However, they happen at a more fundamental level in GM seed and involve a greater dependence on the role of ‘scientific risk assessment’, with all its attendant uncertainties and assumptions (as opposed to e.g. hygiene regulations). Further, people cannot avoid GM foods by growing and cooking their own food if all food and seed supplies (at least of certain crops) become GM, so this loss of autonomy can be imposed on whole populations (in the name of progress).

Releases (or escape) of synthetic or genetically-modified organisms into the environment raise additional concerns due to the self-replicating nature of living organisms and the potential for adverse effects to be irreversible. This is compounded by the complexity of living systems and the difficulties in predicting the consequences of releasing e.g. GM mosquitoes or GM micro-organisms or GM fish into the wild. This leads to broader public concerns about scientists taking control over nature: fed by repeated indications that there are no obvious limits to what will be attempted (even if many applications will in practice not succeed or not survive outside the laboratory or in the market place).

Although some farmers have argued that they should have a right to plant (authorised) GM crops on their own land (exercising their own right to autonomy), there are also concerns about impacts of GM seeds on the autonomy of farmers (including those planting GM and conventional or organic crops). US farmers have suffered a series of seed price hikes and the need to pay for more and more expensive chemicals as the US company Monsanto has gained greater monopoly control over the seed market and

herbicide-resistant superweeds have spread across farmland. Similar problems are beginning to emerge with pest-resistant GM crops. Patented GM seeds cannot be replanted due to licensing agreements, leaving farmers vulnerable to lawsuits for theft of intellectual property, even if seed blows inadvertently onto their land.

Although human gene sequencing is a very different biotechnology, the same issue of dependence arises due to the process of adding economic value through the use of science. In this case, people are dependent on expert interpretation of what their genes mean for their health (or ancestry/paternity) as well as safeguards to protect their privacy and other rights. Because people are currently dependent on their doctors for the interpretation of medical tests, this tension has tended to manifest itself as a dispute between commercial companies and the medical profession, rather than the general public. For example, 23andMe states: “*Twenty years ago doctors had tight control over all medical information. We want that power to shift to individuals*”<sup>18</sup>. But of course, without medical intermediaries, individuals will be dependent on the company to interpret what their genome means: a strategy that is being pursued deliberately because control over diagnostics (and, even better, prognostics!) is seen as key to controlling and expanding the market for medical products and services.

More fundamentally, there are significant opportunity costs to investing in biotechnological approaches to solving problems such as health, crime, obesity and hunger, because there are real limits to what these technologies are able to deliver. For example, salt-tolerant and nitrogen-fixing GM crops were promised in the OTA’s 1982 report, but are still not in the pipeline. Genetic tests are also poor predictors of most diseases in most people (and of adverse drug reactions).<sup>19</sup> Perpetual repetition of claims that cannot be substantiated and are not then delivered tends to lead to loss of public trust in science.

### **9 Do you think that some social and ethical themes are commonly overlooked in discussions about emerging biotechnologies? If so, what are they?**

The main neglected areas are how decisions about research priorities are made; the social and economic impacts of early-stage patenting; the philosophical and scientific assumptions underlying particular research directions (and claims about what these can deliver); and the inherent biological and technical limitations to what can be delivered by any specific technology or approach. Underlying all these areas of neglect is the issue of vested interests: the role of funders, the need for scientists to make exaggerated promises to secure research funding, and the role of patents and venture capital in underpinning a particular model of the role of science in society.

#### *Research funding decisions*

Research funding decisions are *political* decisions, about how to best spend public money, which institutions to support and what incentives to provide to researchers in academia and industry. They raise important social and ethical issues because these investments (both public and private) can open up or close down approaches to tackling problems and because there are significant opportunity costs to making poor investment decisions. However, the political endorsement of biotechnologies as a key driver of innovation and competitiveness is often taken as a given in social, ethical and political debates. For example, the House of Commons Science and Technology Committee



stated in its 2010 Bioengineering report that bioengineering “*virtually ‘picks itself’ as an area in which the Government should be investing heavily*”.

This problem has been exacerbated by research funding structures which tend fund social scientists and ethicists to study the ethical and social consequences of particular commitments to science and technology but not to question why these commitments are being made in the first place. An obvious example is UK Biobank, which has been extremely controversial amongst geneticists and medical researchers, but which was promoted by ethicists and funders (notably the Wellcome Trust) as a project that would bring enormous benefits to health, provided it was implemented in an ethical way.<sup>20</sup> This closed down debate about the scientific merits of the project, and about its political role as a pilot project for creating a genetic database of the entire population. This problem arises partly because of political influences via government-funded research bodies such as the ESRC, but also because what counts as ethics in the context of the Human Genome Project has largely been determined by the funders of the project (the National Institutes of Health in the US and the Wellcome Trust in the UK). Both these institutions are leading advocates of the idea that everyone will one day have their entire genome sequenced and that this will deliver major benefits to health: despite the fact that the health benefits of this approach are strongly disputed and not supported by a growing body of evidence in the scientific literature.

Scientists working in human genetics in particular have published strings of critical journal papers but are discouraged from speaking out for fear of “biting the hand that feeds them” and/or because science journalists have regarded their central role as promoting exciting new discoveries, rather than questioning assumptions or reporting scientific disputes and assumptions.

Due to the previous government’s focus on biotechnology, other forms of innovation (which do not lead to marketable products) have tended to be neglected (e.g. surgery, engineering) and, particularly in agriculture, skills have been lost (soil science, farmland management). This means that there may be significant opportunity costs associated with prioritising R&D investments in the bioeconomy over alternative approaches.

### *Early stage patenting*

A number of social and ethical issues related to the patenting of life forms and genetic sequences have been widely discussed. However, the discussion of the shift to early-stage patenting of scientific discoveries (rather than marketable products) has often been limited to concerns about restrictions on science or access to technologies, rather than the important social and economic impacts of this shift on research priorities and indeed on the whole nature of the process of science and innovation.

Gary Pisano of Harvard Business School explains how three interrelated forces drive the business of (medical) biotechnology:

- (1) the transfer of technology from universities to the private sector through the spawning of new firms;
- (2) capital markets, including both venture capital and public equity;
- (3) the market for know-how in which younger companies trade intellectual property (IP) for funding through various forms of alliance with more established enterprises.

This system allows investors to profit from betting on the ups and downs of the market (i.e. from speculation) in a way that is disconnected from market fundamentals (i.e. supply and demand), in a manner that is similar to the process that caused the credit crunch and (in the case of speculation in food commodities) has been blamed for contributing to food price hikes that have pushed millions into hunger. Instead of using competition and the profit motive to provide incentives to develop the best products, this system has tended to enrich a small number of individuals whilst proving a net drain on the economy.

The creation of a speculative market based on selling the *promise* of technologies (rather than technologies themselves) means that value for investors can be generated even in the absence of any useful products (provided they buy and sell at the right time).<sup>21</sup> Senior managers (often including the scientists named as inventors on the patents) can also draw large salaries, even though most biotech spin out companies never deliver on their promises.

#### *Philosophical and scientific assumptions and inherent biological and technical limitations*

A simplistic view of the role of genes in plants, animals and humans has underpinned the model of innovation which was supposed to drive significant expansion in the biotechnology industry.

For example, the whole of human genetics still rests on the equations used by the eugenicist Ronald Fisher to calculate the heritability of complex traits.<sup>22</sup> These equations give (at best) an upper limit to the genetic component of the variance.<sup>23</sup> Thus the entire enterprise is based on hunting for genes that may not exist (to explain the 'missing heritability'<sup>24</sup>) and which will have low predictive value and limited clinical utility even if they do exist.

The idea that collecting more and more data (genetic, epigenetic, electronic medical records) will allow biology to morph into a predictive science by feeding all the numbers into computers has recently been critiqued in Adam Curtis' BBC series *All Watched Over by Loving Machines of Grace*. It is no coincidence that 23andMe is based in California, where such ideas are now deeply rooted in the culture. From a scientific point of view this (and the idea of 'hypothesis free science' which underpins it) is of course a nonsense because the data could theoretically be combined in an infinite number of ways, there is no way for the predictions to be validated, and complex systems are not deterministic but have limited predictability. When applied to human behaviours, Fisher's equations assume that free will does not exist, and neither do social interactions: assumptions that are in fundamental conflict with most people's everyday experience.

Similarly, the idea that salt- or drought-tolerance can be engineered into plants neglects the role of complex interactions between multiple biological and environmental factors.

#### **10 What evidence is there that ethical, social and policy issues have affected decisions in (i) setting research priorities, (ii) setting priorities for technological development, and (iii) deploying emerging biotechnologies, in either the public or private sector?**

A strong political commitment to developing the bioeconomy has underpinned the process of setting priorities for research and for technological development. However,

when it comes to deploying emerging biotechnologies many other factors come into play, largely because ordinary people are faced with day-to-day decisions about whether and under what conditions they will accept such technologies e.g. whether to eat GM foods or take a genetic test. Institutions such as the NHS, professionals groups ranging from farmers to nurses, regulators and civil society organisations all form opinions and take part in an (often highly contested) debate about the pros and cons of using the technology and what controls are needed.

There is therefore little evidence that public concerns have any influence on priorities for research or technological development, but examples of effects on deployment are numerous. Since many of the technical, social, ethical and economic issues that arise can be anticipated, this begs the question why they are not taken into account earlier in the innovation process, with a view to actually changing investments and outcomes (rather than informing new PR strategies and further lobbying and political strategies to generate acceptance or seek to make implementation inevitable).

When technologies fail to deliver or are not taken up by the market, opponents tend to be blamed for blocking progress. Failure is then treated as a problem that must be overcome with yet more investment or subsidy, weaker regulation, stronger IP protection, increased policy commitment and PR exercises to convince the end users that they should accept it (either as beneficial or simply as inevitable). Members of the public, campaign groups and even health professionals (in the case of genetic testing) have tended to be treated as ill-informed and in need of more 'education' (the 'deficit model' of public understanding of science). This system is a waste of money because real problems (technical, ethical or social) that have often been anticipated are not allowed to alter the course of development of a technology or investments in it, but come into play only when attempts are made to recoup those investments by bringing the technology into the marketplace or the NHS.

One example is the series of (so far unsuccessful) attempts that have been made to sequence DNA collected in the NHS without consent in order to implement the vision of a society in which everyone will have their entire genome sequenced. In the UK, the idea was first proposed by Sir George Poste in 1999 and endorsed by the House of Lords Science and Technology Committee: their disastrous proposal to try to emulate DeCode's biobank in Iceland in the NHS led to a £12 billion plus commitment to building a central database of electronic medical records in the NHS: now widely recognised to have been one of the major financial disasters of the Blair/Brown government. (DeCode itself was declared bankrupt in 2009<sup>25</sup>). Proposals to sequence the DNA of every baby at birth (in the NHS Genetics White Paper in 2003) had to be abandoned. Subsequently, data-sharing proposals made by Wellcome Trust Director Mark Walport at Gordon Brown's request in 2008 and hidden in Clause 152 of the Coroners and Justice Bill in January 2009 caused a public outcry and were dropped like a hot potato.<sup>26</sup>

There is of course ample evidence that, in general, the public do not wish their data to be used without consent and that genetic sequencing is largely useless as a general screening tool (although not without some useful applications). Recent European polling found that close to nine out of ten Europeans think that genetic information such as DNA data should have the same special protection as data related to health, sex life, ethnic origin, religious beliefs, and political opinions; almost all Europeans believe that under-age children should be specially protected from the collection and disclosure of personal data; and most want to restrict access by the police.<sup>27</sup> Yet, this evidence is never

allowed to change the vision and result in a shift in investment into something else. Attempts to access DNA and data in electronic medical records in the NHS without consent therefore continue as if nobody will object and there is no real problem with the science: recent proposals have been made by the Academy of Medical Sciences (headed by Professor Sir John Bell), the Human Genome Strategy Group (HGSG also headed by Bell) and (again, but not in public) by the Wellcome Trust. Although presented to the public as being about allowing access to 'researchers', such proposals neglect to mention that companies such as Google (which want to data-mine medical records and DNA samples) now count themselves as researchers and have been discussing access to NHS samples with the Department of Health.

In the US, retention of babies' blood spots for research use without consent under the Newborn Screening Saves Lives Act has already caused controversy. It remains to be seen whether attempts to 'educate' the public to believe that this idea is all for the own good and nothing to do with building a genetic database will be successful.<sup>28</sup> Such attempts at 'education' of course sit uneasily with commercial claims that genetic mapping of every baby will become the norm (and that loss of privacy if this happens is inevitable).<sup>29</sup> Yet another proposal to use 'by-products' of health-care, linked to electronic medical records, for genetic research was made recently by Isaac Kohane of Harvard Medical School in *Nature Reviews Genetics*<sup>30</sup>.

### ***Ethics***

#### **11 What ethical principles should be taken into account when considering emerging biotechnologies? Are any of these specific to emerging biotechnologies? Which are the most important?**

Autonomy is discussed at length above.

Honesty, integrity and responsibility are rarely mentioned. Perhaps they should be in a world where Oxford Capital Partners offers investors a variety of tax benefits including 20% income tax relief (on investments up to £500,000); tax-free profits and exemption from inheritance tax (after two years) and former science minister Lord Drayson (also a major donor to New Labour) is reported to have saved saved £1 million in tax by setting up a charity to manage his biotech investments.<sup>31</sup>

#### **12 Who should bear responsibility for decision making at each stage of the development of an emerging biotechnology? Is there a clear chain of accountability if a risk of adverse effects is realised?**

Accountability for adverse effects is often realised only via provisions for economic and environmental liability. These provisions are generally limited and also come into play only after harm has occurred, without affecting earlier decisions on investments or potential applications. There is little accountability because at the end of the day consumers or intermediaries (such as farmers) will bear the risk if biotechnologies fail or cause harm to the environment or human health.

Investment decisions are even less accountable. For example, the House of Lords Science and Technology Committee has never even been asked to justify why it persuaded Tony Blair to spend £12 billion on a centralised database of electronic medical records, let alone to repay all this taxpayers' money!

## ***Policy***

### **13 What roles have ‘risk’ and ‘precaution’ played in policy decisions concerning emerging biotechnologies?**

In general, debates about ‘risk’ and ‘precaution’ have been central to debates about biotechnologies. Although these debates are important, the role of misleading claims about benefits (and the science funding system which supports these<sup>32</sup>) has tended to be ignored, as has the role of vested interests in promoting particular approaches.

For example, open releases of GM mosquitoes raise important issues about risk prediction, scientific uncertainty and ignorance and the need for a precautionary approach.<sup>33</sup> However, a focus on how these issues are to be weighed up in order to inform regulatory decisions neglects the issue of why this particular approach has received so much investment (both former UK science minister Lord Drayson and former President of the Royal Society Bob May have acted as advisors to investors in the company), how a British Overseas Territory (exempt from both the Cartagena Protocol and the Aarhus convention) came to be chosen as the site for the first open release of GM mosquitoes in the world, and the implications of Oxitec’s business model (which assumes its developing country customers will be locked in to ongoing payments for repeated releases of millions of GM mosquitoes, allowing it to repay a major loan and pay dividends to its investors, including Oxford University).<sup>31</sup>

An estimated 40% of GM maize in the US is now going to biofuels production, with most of the remaining GM food crops going into animal feed. This diversion of potential food-growing land to produce industrial-scale biofuels and animal feed is one factor in perpetuating global hunger.<sup>34</sup> Yet the role in lobbying for biofuels subsidies by Monsanto and other US agri-businesses is not captured in a narrow debate about managing risk.

There are many more examples, some highlighted above.

### **14 To what extent is it possible or desirable to regulate emerging biotechnologies via a single framework as opposed to individually or in small clusters?**

Regulation needs to be appropriate to the particular application. However, the broader concept of the bioeconomy and the visions of the future that it encompasses can be debated as a single over-arching framework.

## ***Public engagement***

### **15 What role should public opinion play in the development of policy around emerging biotechnologies?**

Decisions about emerging biotechnologies (including research investment decisions) must be more democratically accountable. This requires greater public scrutiny, rather than allowing decisions to be made by a small circle of advisors with vested interests in particular approaches. Democracy is messy and there is no magic bullet to avoid mistakes and reach the right decisions. However, a better approach would involve:

- Openly recognising conflicts between different interests and investment priorities and the need for policy trade-offs, necessitating political decisions;
- Recognising governance and regulation as part of the system that influences who bears the costs and risks, or reaps the benefits, of innovation;
- Advocating approaches that examine and decide these trade-offs in a fair, democratic and transparent way;

- Viewing economic benefits as being rooted in society – for example, supporting rural economies and livelihoods – rather than in terms of gains for venture capitalists or city traders, or growth in particular industrial sectors such as food manufacture or pharmaceuticals.

Objectives should include:

- More democratic decisions about research funding priorities and a more diverse research agenda;
- Greater accountability and scrutiny of major research investment decisions: including economic assessments and appraisals, scrutiny of scientific and technical assumptions, and active steps to prevent political ‘entrapment’ in research agendas based on false assumptions and misleading claims;
- A role for public engagement in setting research questions and priorities, including consideration of a variety of alternative approaches to addressing problems, and greater democratic accountability for science policy decisions;
- More public engagement in research itself, involving closer co-operation between universities, communities and civil society organisations;
- More funding for research which does not necessarily benefit large corporations but may deliver other benefits including economic ones (for example, public health research, and research into improving agro-ecological farming methods);
- Funding for ‘counter-expertise’ and multi-disciplinary research which can identify long-term scientific uncertainties and regulatory gaps;
- Ensuring a thriving scientific culture that can analyse, critique and develop the theoretical concepts that often underlie decision-making, and which are key to developing new understandings;
- A commitment to taking public opinions into account in decisions about science and innovation, including methods to ensure full consideration of the broader social, environmental and economic issues associated with adopting particular approaches and technologies.

### **16 What public engagement activities are, or are not, particularly valuable with respect to emerging biotechnologies? How should we evaluate public engagement activities?**

It is easier to state what is not valuable than what is valuable because activities to date, whilst often leading to interesting and valuable discussions, have usually been set up with a view to maintaining the existing system of decision-making, rather than actually changing research priorities or the way decisions are made.

The European Commission-funded project ‘Participatory science and scientific participation: The role of civil society organisations (CSOs) in decision-making about novel developments in biotechnologies’ (PSx2) involved people from CSOs (including GeneWatch UK) and academics in a study about participation in science in the context of novel biotechnologies (with an emphasis on GM crops).<sup>35</sup> Although the original intention of the project was to focus on ‘good practice’ in participation, it found that CSOs believe themselves to be operating within a structure that fundamentally denies them opportunities for meaningful participation. As we have argued above, this is largely due to the prior commitments and enormous investments (of money, infrastructure and personnel) made in the bioeconomy, which leaves critics largely powerless to influence

events except through protest and other actions which damage the market for contentious biotechnologies long after taxpayers' money has been wasted.

The people who were interviewed in the PSx2 project (members of CSOs) believed that there is a need to re-examine the way science feeds innovation so that the whole process is more transparent and equitable. The project identified ten principles for effective participation:

- **Funding for scientific research should be allocated according to 'public interest'** and the needs of the final user.
- **Early participation of civil society, at a meta level**, when the terms of the innovation process are non-technical.
- **Everyone could, and should, be able to participate** at some level and in some capacity and this would necessarily include Civil Society Organisations as 'stakeholders'.
- **Participation must be on an equal footing** to address unequal power relations.
- **Two way exchange of information, open mindedness and genuine engagement**, by the scientific institutions, between themselves and citizens.
- **Debates about science should involve different opinions/viewpoints** and a plurality of expertise and recognition of other types of knowledge that take into account minority opinions.
- **Openness and transparency are crucial** in the development and practice of publicly funded scientific research and its regulation.
- **Easily accessible and non-technical information is required.** The public needs to be given the opportunity to acquire a good understanding of the technical issues.
- **Participation in science requires consideration of specific interests and ways of life** e.g. women's perspectives and specific requirements and farmer's needs and timetables.
- **Public participation in science requires evidence that public concerns have been listened to** and taken into account.

This research focused on a subset of people (critics of novel biotechnologies in CSOs) so is obviously not representative. However, it highlighted widespread agreement amongst this sector of society that fundamental changes are needed in decision-making processes.

**17 Is there something unique about emerging biotechnologies, relative to other complex areas of government policy making, that requires special kinds of public engagement outside the normal democratic channels?**

Science and technology policies in general have tended to lack transparency and democratic accountability to a far greater extent than many other areas. In some cases policy making could be described not merely as undemocratic but as anti-democratic, with policy approaches tending to exclude the public on the grounds that they are not experts: voters may even be portrayed as anti-science, anti-progress or irrational.

Whilst public and democratic scrutiny has been avoided, vast sums of taxpayers' money have been invested in subsidising the bioeconomy. Biotechnologies are acknowledged to raise many social and ethical issues and sometimes to be highly controversial. Further, many biotechnologies have not delivered on their promises, have unpredictable

effects on health and the environment, are not cost-effective, and/or have failed in the market place.

These issues are not unique to biotechnologies (another example would be nuclear power) but the significant political commitments made at both a national and international level to the idea of a new bioeconomy necessitates wider public scrutiny.

At the same time, there will be real limits to what public engagement can achieve “outside the normal democratic channels”. To be effective, public engagement processes must feed in to policy-making via strengthened democratic processes, leading to more accountable decisions.

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