

## Twenty-first Century Governance Challenges in the Life Sciences

### BIOTECHNOLOGY ADVANCEMENT IN THE TWENTY-FIRST CENTURY

Depending on its application, biotechnology falls into three broad categories: ‘red’ biotechnology encompassing R&D in medical and healthcare sectors (e.g. drug development, disease diagnostics, prevention and treatment); ‘green’ biotechnology related to agriculture (e.g. increasing plant resilience to drought, herbicides and pesticides); and ‘white’ biotechnology covering innovation for industrial purposes (e.g. environment-friendly products).<sup>1</sup> The expansion of all three types of biotechnology over the past several decades has been truly breathtaking, both in qualitative and quantitative terms. Forty years ago scientists were fascinated to manipulate the manifestations of life by dint of gene-splicing, while the tools and technologies available in the beginning of twenty-first century have enabled them to *create* life forms from scratch.<sup>2</sup> Similarly, when initially conceived the Human Genome Project (HGP) seemed a daunting undertaking, but within less than ten years of its completion the areas of genome-based diagnostics and therapeutics are now growing at a remarkable pace; and if once cutting-edge life science research used to be confined to prestigious universities and state-of-the-art laboratories found in the highly industrialised countries in the global North, nowadays studies involving highly dangerous microbes are conducted in research facilities scattered around the globe from Indonesia and Vietnam through Kenya and Morocco to Moldova and Pakistan. One authoritative high-level review has even gone

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so far as to suggest that the ‘life sciences knowledge, materials and technologies are advancing worldwide with Moore’s Law-like speed.’<sup>3</sup> And whilst some commentators have questioned the extent to which the ongoing progress of biotechnology has translated into practical applications and novel products,<sup>4</sup> there is some consensus that the biotechnology landscape has been fundamentally transformed over the recent decades with the possibilities now unlocked holding revolutionary potential. Indeed, rapid advances in the field have produced a knowledge base and set of tools and techniques that enable biological processes to be understood, manipulated and controlled to an extent never possible before<sup>5</sup>; they have found various applications in numerous spheres of life, generating enormous benefits and offering bright prospects for human betterment; and they have come to be regarded as a key driver of economic development with potential to close the gap between resource-rich and resource-poor countries.<sup>6</sup>

The progress of biotechnology has been largely driven by three sets of forces, namely social, political and economic.<sup>7</sup> The social dynamics at work in this context are understood as the efforts to improve public health and overall wellbeing of individuals both in the global North and global South, boost agricultural yields and encourage environment-friendly practices to mitigate the adverse effects of climate change. Several factors account for the significant value attached to the life sciences in the context of intense globalisation and continuous change. Surging population numbers and extended life expectancy are augmenting the demand for developing effective and affordable medications, novel approaches for the treatment of chronic diseases and additional cost-effective sources of energy and food production. At the same time, rising global trade and travel, coupled with increased urbanisation, and an uneven distribution of wealth are creating optimal conditions for disease outbreaks, pandemics and environmental degradation.<sup>8</sup> Against this backdrop, biotechnology appears full of promise and critical to tackling social and natural concerns; enhancing disease prevention, preparedness and surveillance; promoting development; and alleviating human suffering.<sup>9</sup>

Economic dynamics include national expenditure on research and development, purchasing power, trends in consumerism and market pressures and fluctuations. Besides public funding for R&D which remains a key factor in the growth and flourishing of bioindustry in developed and emerging economies alike, private investment from venture capital firms, start-up companies and transnational corporations (TNCs) have also

played an indispensable role in capturing new markets and further facilitating the extension of bioeconomy on a global scale. DuPont's significant footprint in India is indicative in this regard, not least because of the depth and diversity of the activity that the company has undertaken via its offshore R&D centres ranging from crop science to biofuels.<sup>10</sup> Likewise, Merck has outlined a 1.5 billion dollar commitment to expand R&D in China, as part of which it intends to establish an Asia headquarters for innovative drug discovery in Beijing.<sup>11</sup>

Political dynamics are triggered by states' increasing commitment to support the progress of biotechnology as a way of maximising their power and boosting their status in the international arena.<sup>12</sup> In the aftermath of 9/11 and the 'Anthrax letters' attack of October 2001, substantial effort has been given to harnessing life science research for the purposes of national security. Biodefence and bioterrorism preparedness are thus considered high-priority areas for national investment by government agencies and the military alike. An illustrative example of this two-tiered approach is the funding policy in the USA, where biodefence research is financed by the NIH, Department of Homeland Security (DHS) and Defense Advanced Research Projects Agency (DARPA), to name a few.

Under the synergistic influence of these three sets of forces – social, economic and political – biotechnology has been transformed into a truly global fast-evolving enterprise encompassing a multitude of stakeholders, delivering considerable benefits and holding out still greater promise, with profound and far-reaching implications for virtually every aspect of human well-being and social life.

The pharmaceutical industry is a case in point, for its steady expansion would hardly be possible were it not for the vast array of techniques and methods enabled by the progress of the life sciences. Worth roughly 400 billion dollars, the global pharmaceutical market dominates the life sciences industry and arguably determines the trajectory of life sciences-related technological development and global spread.<sup>13</sup> Gene cloning, DNA sequencing and recombinant construction of cell lines, to name a few, are all deemed indispensable for the development of novel medicines and therapeutics. It suffices to mention that more than half of the top selling commercially available drugs in the USA would not exist without those methods.<sup>14</sup> Agriculture, too, has been heavily influenced by the ongoing biotechnology revolution, as evidenced in the rapid growth and dispersion of commercialised transgenic crops (biotech crops) and the efforts to use GMOs (both animals and plants) for the production of

vaccine antigens and other biologically active proteins ('biopharming').<sup>15</sup> Indeed, the increase in the area of farmland planted with transgenic crops rose dramatically from 1.7 hectares in 1996 to about 60 million hectares in 2002<sup>16</sup> and is still growing. In addition, technological convergence<sup>17</sup> between biotechnology, nanotechnology, information technologies and cognitive science has unlocked a broad scope of opportunities for maximising public (and private) welfare, offering substantial benefits in wide-ranging areas such as medicine, pharmacy, crime investigation and national security by ensuring precision and reliability, while at the same time, reducing the amount of time previously required for the performance of certain tasks.

Four key features of biotechnology make it so appealing to the majority of stakeholders involved. First, biotechnology innovation is characterised by *duality*, whereby research yields results that simultaneously lead to advances in basic knowledge and stimulate product development.<sup>18</sup> Second, the output that the life sciences generate in the form of new medicines, improved nutrition products, enhanced yields and novel materials, is 'strongly positive'.<sup>19</sup> The increasing utility of tools and strategies for human enhancement, whether in professional sport, for cosmetic and aesthetic purposes, or on the battlefield, vividly reflects the firm conviction that the transformative capacity of biotechnology, even at the most fundamental level, is something to be welcomed and vigorously embraced. What is more, biotechnology possesses proven economic viability, as illustrated in the burgeoning industries and new markets it has spurred. Against this backdrop, the high rate of biotechnology expansion is anything but surprising, since

every increment in biological capability pays back the researcher and the researcher's sponsors in short order. Payback comes in the esteem of peers, in promotions, and in increases in the academic or corporate salaries of the researchers whose work generates knowledge and new therapies. Payback comes in the form of profits for the manufacturers of kits to perform the manipulations, royalties for the writers of the methods manuals profits for the drug industry. Payback comes for the public in the form of new drugs and therapies.<sup>20</sup>

Fourth, besides being cost-effective, many of the benefits that biotechnology offers are easy to obtain and disseminate. In other words, many of the various prospects for public (and private) betterment are not situated at

some distant moment in the future but can be realised immediately, as a result of which pressing problems can be alleviated, if not fully resolved, and substantial revenue can be generated in the short term. Last but not least, while there are some risks and concerns associated with the advancement of biotechnology, few of those are deemed urgent or significant enough to impact on the pace of innovation. As the actual manifestation of such risks is often contingent upon the interplay of a variety of factors, this renders the likelihood of a major crisis unfolding as a result of the progress of biotechnology low. Moreover, there is a genuine belief that any challenges that may arise from the proliferation of novel technologies can either be foreseen or dealt with on a case-by-case basis. Given the enormous potential of biotechnology for addressing societal, economic and environmental challenges, it is unsurprising that most states have readily endorsed scientific and technological innovation and embarked on large-scale generously-funded R&D programmes in the life sciences.

## TRENDS IN BIOTECHNOLOGY GOVERNANCE

Given the powerful multifaceted impetus for biotechnology advancement, it is possible to identify at least five key trends in the governance of biotechnology that are common for highly industrialised and developing countries alike. Those include: high-level coordination, facilitation and funding; synergies within and between both the public and private sector; emphasis on strategic and competitive interests at the expense of precaution; regulations that seek to promote rather than restrict scientific and technological progress; and overreliance on technical solutions.

### *High-Level Coordination, Facilitation and Funding*

At international level, the on-going expansion of biotechnology has been hailed not only as an inherently positive development but also as an essential prerequisite for enhancing human welfare and addressing various socio-economic, environmental and health concerns. In its 2013 World Health Report, the WHO called for:

Increased international and national investment and support in [life science] research aimed specifically at improving coverage of health services within and between countries.<sup>21</sup>

The WHO has also strived to promote research on specific diseases, such as HIV/AIDS, cancer, pandemic influenza, tuberculosis and malaria, with the goal to improve methods for prevention and diagnostics and facilitate the development of effective therapeutics and vaccines.<sup>22</sup>

In a similar fashion, the UN Food and Agriculture Organisation (FAO) has highlighted the positive impact that biotechnology could have on the development of agriculture:

...biotechnology could be a major tool in the fight against hunger and poverty, especially in developing countries. Because it may deliver solutions where conventional breeding approaches have failed, it could greatly assist the development of crop varieties able to thrive in the difficult environments where many of the world's poor live and farm.<sup>23</sup>

It is not difficult to see how those assertions have been translated into national policies and practical steps across the globe. The US NIH that provide the bulk financial support for medical and health-oriented R&D in the US spent over 30.9 billion dollars during the fiscal year 2012, about a third of which was allocated for funding biotechnology and bioengineering projects.<sup>24</sup> Within its Sixth Framework Programme for Research and Technological Development spanning the period 2002–2006 the European Union (EU) distributed more than 2.5 billion euro for projects under the theme 'Life Sciences, Genomics and Biotechnology for Health'.<sup>25</sup> Developing countries, too, are increasingly investing in 'red' biotechnology as part of their efforts to address public health concerns. According to a recent WHO report, support for biotechnology and particularly, for cancer research, in Cuba has soared over the past 20 years, amounting to over one billion dollars.<sup>26</sup> As a result, the Cuban biotechnology industry is burgeoning, holding around 1200 international patents and exporting vaccines and pharmaceuticals to more than 50 countries.

The prospect of climate change coupled with rising population numbers has compelled governments in the global North and South alike to explore 'green' biotechnology as a means of ensuring food security. The USA remains by far the largest commercial producer of GM crops. Several EU member states (France, Germany, Spain, Poland, Romania, Czech Republic, Portugal and Slovakia), Canada and Australia further feature in the list of industrialised nations that have embarked on growing GM plant breeds. More and more emerging economies are striving to expand their agrobiotechnology sector, most notably Brazil, India, Argentina, South

Africa, Mexico, Burkina Faso, Myanmar and Chile.<sup>27</sup> In 2008, the Chinese government launched a major R&D initiative worth 4 billion dollars to develop new plant varieties by 2020 that will enhance yields, have improved nutritional value and be resistant to pests.<sup>28</sup>

### *Synergies Within and Between Private and Public Sectors*

Public-private partnerships underpinned by access to early-stage risk capital and strong linkages between business, universities and entrepreneurial support networks constitute an important vehicle for promoting innovation and fostering technology transfer and product development. For instance, the Chinese government has launched a major initiative mobilising 2.5 billion dollars in venture capital to support start-ups in the immense Zhangjiang science park outside Shanghai<sup>29</sup>; Russia's Rusnano has entered a 760 million dollar partnership with the US venture capital firm Domain Associates to fund 'emerging life science technology companies and establish manufacturing facilities in Russia for production of advanced therapeutic products'; and Cleveland's University Hospital has allocated 250 million dollars for setting up a 'non-profit entity to fund and advise physician-scientists on transitional research and a related for-profit accelerator that will develop selected compounds to proof of concept.'<sup>30</sup> The Kauffman Foundation in the USA, a wealthy philanthropic establishment dedicated exclusively to the goal of entrepreneurship has been particularly zealous in its quest for promoting university-based entrepreneurial activities nationwide. Its Kauffman Campuses Initiative launched in early 2003 enjoyed so much popularity among universities that following the initial round of grants totalling 25 million dollars, the Foundation announced its resolve to leverage a 100 million dollar investment for the creation of new interdisciplinary education programmes.<sup>31</sup>

University-industry partnerships, while not a novel phenomenon in the area of biotechnology, have considerably intensified over the past several decades, thus facilitating the widespread commercialisation of life science research. Indeed, 90 per cent of the companies in the US surveyed by Blumenthal et al. in 1996 had relationships with an academic institution in that year and in more than half of those cases industry provided financial support for research in such institutions.<sup>32</sup> According to another study, the total industry investment in academic life science research in the USA tripled between 1985 and 1998 reaching almost 2 billion dollars and has been growing ever since.<sup>33</sup>

Against this backdrop, some commentators have put forward the ‘Triple Helix’ model, which serves both as a conceptual tool and a policy blueprint. In the former case, it is used to elucidate the academic-industry-government relationships that underpin the institutional arrangements and changing practices in the processes of production, transfer and application of knowledge in post-industrial societies; in the latter, it is promoted as a framework for economic development through state investment and knowledge sharing between academia and industry.<sup>34</sup>

Others, however, have remained sceptical of the close integration of universities and the private sector voicing concerns about the possible deleterious effects arising therefrom:

As in other activities, when big money flows fast, temptations and opportunities arise for risky behaviour and stealthy or even brazen wrongdoing in pursuit of personal or institutional advantage. The new world of academic-commercial dealings is characterised by some grey areas and evolving rules for permissible and impermissible conduct. The people who manage and conduct research in scientific organisations are not immune to the weaknesses and foibles so plentiful elsewhere, despite the accolades for probity that science bestows upon itself.<sup>35</sup>

With more and more universities joining the biotechnology ‘gold rush’ and corporate values and goals steadily penetrating the professional academic cultures, scholarship turns into a result-oriented activity subject to the priorities and interests of business partners and industrial sponsors. Strategy and careful planning deemed essential to the pursuit of for-profit knowledge can have a restraining effect on the spontaneous vigour characteristic of academic research, limiting the range of problems that could be studied to those defined by the market.<sup>36</sup> At the same time, scientists often find themselves under tremendous pressure striving to satisfy the demands of their industrial clients without utterly neglecting their academic duties ranging from mentorship through filing grant applications to publishing. The extensive workload coupled with the bright prospects for securing long-term research funding and achieving some individual gain and prominence provide a favourable environment in which instances of dubious, sometimes fraudulent, behaviour, conflicts of interest and lack of transparency, unless too severe, are unlikely to encounter widespread opprobrium and may even go unnoticed.<sup>37</sup> In the race for patents and



venture capital, the business mentality dulls scientific rigour and the ethics threshold appears not too difficult to cross.

*Governments Tend to Favour Strategic, Political and Economic Interests at the Expense of Precaution*

Given the tremendous benefits that biotechnology is expected to generate in virtually any sphere of human activity, it is not difficult to understand why its progress is predominantly viewed through an explicitly positive lens by policy-makers. Since the opportunities for achieving public betterment and enhancing state prestige and international standing are too tempting and too abundant, there is a powerful urge to dedicate both will and resources to promoting the large-scale expansion of the life sciences. For one thing, the prospect of conquering disease and maximising human wellbeing provides solid justification for a deliberate and sustained investment in fostering scientific and technological prowess. Lack of commitment and reluctance to support R&D in the life sciences then becomes an unfavourable option in the political calculations of states regardless of their level of economic development and international status. Within the context of political calculus pervaded by realist fears, competition and power, the perceived risks of inaction with regard to scientific and technological development justify vast expenditure, lower regulatory barriers to innovation and product development. Political choices concerning biotechnology support are therefore frequently made at the expense of calls for caution and potential social, environmental and ethical concerns.

The regulation of genetic engineering is a case in point. As discussed in the previous chapter, from the outset, the attempts of governments to impose strict controls on research involving rDNA faced a severe backlash from academic scientists and business executives alike. By the 1980s, the various legislative initiatives put forward in the USA were abandoned in favour of the regime established by the NIH Guidelines, which virtually exempted the biotechnology industry from formal regulation. While the leading US-based companies pledged to ‘voluntarily comply’ with the Guidelines, behind the scenes they craftily continued to push for a system that would insulate them from governmental and public scrutiny.<sup>38</sup> Indeed, during the 1990s when the States Parties to the BTWC strived to strengthen the treaty by negotiating a binding verification mechanism corporate interests proved too big and too important to be ignored. Both the Pharmaceutical Research and Manufacturers of America (PhRMA)

which represented the country's major research-based pharmaceutical and biotechnology companies, and the Biotechnology Industry Organisation (BIO) which at that time represented some 1400 biotechnology firms, became vocal opponents of any measures designed to promote international arms control which seemed to hinder in any way the protection of proprietary information and intellectual property.<sup>39</sup> In the period between 1994 and 2001 the associations invested considerable effort, time and ingenuity in lobbying the US government and influencing the diplomatic talks in Geneva to secure an outcome that was in line with the demands of their constituencies. Of course, it would be naive to ascribe the US resolve to reject in 2001 both the text of the Protocol and its utility in general for providing adequate verification and enhancing confidence among States Parties solely to the activity of the biotechnology industry; nevertheless, it would be equally naive to suppose that corporate interests played no significant role in the process.<sup>40</sup>

Besides economic priorities, national security and military calculations can also provide a compelling rationale for downplaying the potential risks associated with biotechnology expansion. Following the 'Anthrax letters' attack in October 2001, the US government embarked on a massive financial investment to boost its bioterrorism preparedness and enable the prevention, early detection, monitoring and emergency response to biological threats. As outlined in *Biodefense for the 21st Century*, a presidential directive that set out a comprehensive framework for national biodefence policy, between 2001 and 2005 the federal government provided roughly 6 billion dollars 'to state and local health systems to bolster their ability to respond to bioterrorism and major public health crises'.<sup>41</sup> Along with the highly controversial vaccination programme that the government envisaged,<sup>42</sup> another important development designed to enhance America's biodefence preparedness and capability was the drastic increase both in the number of high-containment labs (BSL-3 and BSL-4) and the number of researchers with access to some of the most dangerous pathogens known to mankind, including the causative agents of Ebola, plague and Q fever. Some commentators have questioned the logic behind this policy highlighting the heightened risk of accidental or deliberate release of pathogens.<sup>43</sup> Far from being ill-founded or hypothetical, such fears stemmed from a range of high-profile cases that occurred after 2001 across the US in which the lack of proper training and professional negligence resulted in scientists being exposed to or infected with deadly microbes.<sup>44</sup> Real-life horror stories about vials of plague being transported

in the hand-luggage of researchers on passenger aircraft without the required authorisation, and deadly cultures gone missing from what appeared to be secure laboratories further fuelled the criticism toward the US biodefence policy raising difficult questions about its appropriateness and actual goals even before the ‘Anthrax letter’ investigation revealed that the attack was ‘insider’s business’.<sup>45</sup>

*Biotechnology Regulations Seek to Promote Rather Than Restrict  
Technological Advancement*

Life science research, just as any other sphere of professional activity, is subject to a range of institutional, national and international regulations. Along with the more general rules such as those related to occupational health and safety, fair pay and job competition, conflict of interests, labour rights, and professional liability, there are also specific ones addressing particular aspects of the research process including project clearing (e.g. review by local biosafety committees), safe laboratory practice and transport of pathogens (e.g. 2005 International Health Regulations), exchange of viral strains (e.g. Pandemic Influenza Preparedness Framework, 2011), handling of dangerous pathogens (e.g. US Select Agent Programme) and ethical treatment of human subjects and samples obtained therefrom (e.g. The 2004 Human Tissue Act in the UK).<sup>46</sup> While hardly exhaustive, this list suffices to convey the idea that the regulatory regime governing the practice of life science research is dense and comprehensive. With more than 30 international organisations overseeing biotechnology from various perspectives,<sup>47</sup> there is a *prima facie* reason to assume that the regime in its current form is sufficiently flexible to accommodate novel advances and hold any potential risks, which they may pose, at bay. Yet in reality over the past decade the opposite trend has prevailed, that is, the existing governance mechanisms have struggled to respond adequately to the proliferation of new scientific developments with multiple adaptive uses and the multiplicity of cutting-edge developments posing profound ethical quandaries. How to account for this discrepancy?

Part of the problem stems from the fact that since at least the late 1970s the regulation of biotechnology has been streamlined so as to become compatible with and not a restriction on continued technological change and economic growth.<sup>48</sup> As such, it rests upon the barely questioned assumption that the progress of biotechnology is inherently good and needs to be harnessed and vigorously promoted. Needless to say, any

measures that seem to slow down or restrain its advancement are deemed undesirable and even detrimental to socio-economic development. Hence, when developing regulations, policy-makers have generally pursued a two-fold objective: first, to promote the safe practice of life science research by reducing any risks arising therefrom both to scientists and the general public; and second, to ensure that any issues that may hinder the expansion of biotechnology are not subject to restrictive legislation.

A vivid manifestation of this approach is the way in which the ongoing debate on ‘dual use research of concern’ – benignly-intended research that seeks to maximise human welfare by responding to health, societal and environmental ills but could also facilitate to the development of more sophisticated and potent biological weapons and enable bioterrorism<sup>49</sup> – has been handled. For more than a decade, researchers, journal editors, security experts and policy-makers have strived to devise oversight mechanisms and governance initiatives that could adequately tackle the challenge of dual use without stifling innovation. Unfortunately, to date their efforts have met with little success, as a result of which virtually each experiment of dual use concern is dealt with separately on a case-by-case basis. This is not to say that there are no similarities across the studies of this kind. On the contrary, a few of the most notable examples follow a similar paradigm, including the creation of a vaccine-resistant strain of the Mousepox virus, the artificial synthesis of the Polio virus, the recreation of the 1918 Spanish Influenza virus and, most recently, the production of a mammalian-transmissible H5N1 Avian Influenza virus (see [Fig. 4.1](#)).<sup>50</sup> All four of them were performed in strict compliance with the rules and procedures in place for laboratory biosafety, biosecurity and biorisk management and under appropriate physical containment conditions; all had passed thorough review by the respective local biosafety and bioethics committees; and all of them were deemed essential in terms of public health benefits. Above all, the ethical and security concerns that the studies have raised go far beyond the laboratory door, posing fundamental questions about how life science research is reviewed, conducted and communicated.

Yet none of the high-profile experiments of concern has proved critical enough to provoke a radical change in the way dual-use research is governed.<sup>51</sup> Three points merit consideration in this regard. The first pertains to the manner in which the dominant discourse on dual use is framed, that is, in purely ethical terms as a dilemma. While bioethics undoubtedly has a role to play in the discussions on dual use, the language

*The Australian Mousepox Virus Study*

In early 2001, the *Journal of Virology* published a report of the creation of a highly virulent strain of the *Ectromelia virus*, the causative agent of mousepox. The work described in the report was carried out by a group of Australian scientists based in Canberra. Its original goal was the development of an infectious immune-contraceptive that could be used against wild mice for the purpose of pest control. To achieve this, the group drew upon previously published work. During the course of the experiment, the researchers unexpectedly discovered that the newly engineered strain of the Mousepox virus, which they created, killed 60% more mice than the parent virus, including mice that had been vaccinated or that had natural immunity. When the research was published, concerns were raised that it could potentially be misapplied for hostile purposes, or even that the same technique could be utilised for creating a more virulent strain of the *Variola virus*, which causes smallpox in humans.

*The Artificial Synthesis of the Polio Virus*

In 2002, a team of scientists led by Dr Eckard Wimmer from the University of New York at Stony Brook announced that they had successfully created a polio virus 'from scratch'. To carry out the research, the scientists 'followed a recipe they downloaded from the internet and used gene sequences from a mail-order supplier'.<sup>a</sup> Once the virus created, it was tested on mice, as a result of which the infected animals became paralysed and died. The study spurred a wide-ranging debate, not least because it drew attention to the possibility of using synthetic biology for constructing de novo viruses for the purposes of bioterrorism.

*The Recreation of 1918 Spanish Influenza Virus*

In 2005, it was announced that CDC scientists, together with colleagues from several research institutions across the USA, had successfully recreated the influenza virus, that was responsible for the 1918 pandemic, which killed between 20 and 50 million people worldwide. Using DNA from a tissue of a flu victim buried in the permafrost in Alaska, the researchers managed to reconstruct the influenza virus and thus study its pathogenesis and properties that contributed to its virulence. Despite the scientific justification that was put forward, critics have argued that the study is 'a recipe for disaster', not least because the availability of the virus' full-genome sequence and detailed method for its reconstruction on the Internet may facilitate its synthesis by a rogue scientist.<sup>b</sup>

<sup>a</sup> David Whitehouse, 'First Synthetic Virus Created', *BBC News*, 11 July 2002, available at <http://news.bbc.co.uk/1/hi/sci/tech/2122619.stm> (accessed 1/02/16).

<sup>b</sup> Jan van Aken, 'Ethics of Reconstructing Spanish Flu: Is It Wise to Resurrect a Deadly Virus?', *Heredity*, vol.98 (2007), pp.1–2.

**Fig. 4.1** Examples of Experiments of Concern

of ‘dual-use dilemmas’ is too abstract to offer appropriate analytical tools for dealing with the issues at play. As discussed above, the questions that dual-use research poses such as data sharing, research funding and project planning are far from hypothetical but they feature explicitly in everyday professional practice. However, the ‘dilemma framework’ automatically strips them of the complex socio-technical arenas in which they have actually presented themselves by laying an emphasis on what action should ideally be taken, rather than what is practically feasible given the circumstances.<sup>52</sup> Moreover, such issues are typically structural in nature for they constitute fundamental elements of the life sciences professional culture, and as such, could hardly be adequately addressed solely at the level of individual researchers. Yet framing social, legal and security concerns in terms of moral dilemmas allows for structural issues to be omitted from the discussion, rendering life scientists the chief, if not the only, moral agents expected to reach what is deemed to be the ‘right’ answer.<sup>53</sup> Assigning abstract duties then comes to be regarded as an appropriate ‘solution’, even if those are virtually impossible to fulfil given the complexities of the working environment within which researchers operate.

The second point is related to the reductionist view that dominates the discourse of what counts as a risk in life science research. Perhaps one of the most significant legacies of the Asilomar Conference on rDNA (see [Chapter 3](#)) is the emphasis on laboratory risk that could be effectively managed by dint of physical containment and rules and procedures for safe laboratory practice.<sup>54</sup> It suffices to mention that the bulk of guidelines and formal regulations published by the WHO focus exclusively on promoting and refining measures that aim to maximise laboratory biosafety and prevent the accidental release of pathogens. Hence, it is hardly surprising that the concept of dual use and the idea of risks *beyond the laboratory door* implicit in it seem alien to the majority of practising researchers. Striking as it may appear, even though dual use research has been debated for more than a decade now, the level of awareness among life scientists of the broader social, security and legal implications of their work remains low.<sup>55</sup>

The third point deals with the way in which risks in life science research are assessed and mitigated. Given the narrow definition of risk encompassing technical particulars, physical containment and biosafety, risk assessment is considered an appropriate and reliable tool for ensuring research safety. The heavy reliance upon risk assessing tools is underpinned by two underlying assumptions. One is that it is possible to foresee and calculate most, if not all,

things that could potentially go wrong both during the development phase of the project and after its completion. The other is that it is possible then to use the produced data as a basis for devising measures and strategies for eradicating, or at least, mitigating the risks likely to occur. Attractive as it may seem, this 'new alchemy where body counting replaces social and cultural values' presupposes a clear distinction between the risk assessment 'experts' and the general public, whereby the former are granted a licence to make decisions about the risks that the latter cannot do without.<sup>56</sup> Likewise, cost-benefit analysis on the basis of which research proposals are screened for potentials risks and security concerns has attracted some serious criticism. In the view of some commentators, besides being sometimes deeply inaccurate, the cost-benefit analysis is 'ethically wrong' since 'applying narrow quantitative criteria to human health and human life' is unacceptable.<sup>57</sup> But there are other problems, too. As pointed out by Dickson, the cost-benefit analysis distorts political decision-making by omitting any factors that cannot be quantified, thus obscuring questions of equity, justice, power, and social welfare behind a technocratic haze of numbers.<sup>58</sup> As a result, complex and politically charged decisions are reduced to a form that fits neatly into the technocratic ways of making regulatory decisions, whereby calculations and approximations made by the few substitute for the judgements of many.<sup>59</sup>

The wide-ranging controversy that unraveled in late 2011 when two teams of scientists working independently in the Netherlands and the USA managed to produce an air-borne strain of the H5N1 Avian Influenza virus, a highly pathogenic and lethal microbe with over 60 per cent mortality rate in humans arguably constituted the pinnacle of the deliberation on dual use research. Both studies set alarm bells ringing for the security community who almost immediately jumped in the debate voicing concerns over the possibility of biological proliferation and bioterrorism. Some commentators even argued that the experiments ran counter to the spirit if not to the letter of the 1975 BTWC.<sup>60</sup> Against this backdrop, the resultant controversy was deemed at least initially to offer a timely opportunity to evaluate the existing governance mechanisms, determine their gaps and weaknesses, and broaden the scope of deliberation inviting participation of a wide range of stakeholders. Unfortunately, the outcome of the debate proved far more moderate, signalling preference for preserving the *status quo* without disrupting the established systems for governance and oversight. Despite the extensive mass media coverage of the controversy, only few public consultations were held and none of those was designed as a platform for making

policy proposals or developing action plans. Moreover, the densely-packed agenda prepared duly in advance left very limited scope for posing ‘tricky’ questions which the participating ‘experts’ might have struggled to answer. Needless to say, all consequential decisions were made behind closed doors away from public scrutiny and on some occasions the people with the greatest vested interest in the publication of the studies were also the ones with the greatest say in the process.<sup>61</sup> There were no significant changes in terms of governance initiatives, either. Far from being ground-breaking developments, the US Government Policy for Oversight of Life Sciences Dual Use Research of Concern<sup>62</sup> and the decision of the Dutch government to invoke export control legislation before allowing the publication of the study conducted within its jurisdiction were little more than desperate moves that aimed to obscure the inadequacy and shortcomings of the measures already in place.<sup>63</sup> Overall, the manner in which the H5N1 debate was handled could be treated as a missed opportunity, whereby those in charge of the decision-making process did little to address or even acknowledge the broader issues underpinning dual-use research of concern but simply ‘kicked the can down the road to the next manuscript’ waiting for the next controversy to erupt.<sup>64</sup>

### *Reliance on Technical Fixes*

Technology seems to play a significant role in the governance of life science research. High-containment laboratories, well-equipped biosafety cabinets, sophisticated waste management systems, enhanced personal protective equipment and secure containers for the safe storage and transportation of biohazard materials are just a few of the tools and systems in place that allow the safe handling of dangerous pathogens and toxins and, at the same time, protect both laboratory personnel and the general public from exposure to deadly microbes. That said, the effectiveness of technical solutions should not be overstated if only for the fact that ‘problems’ of governance are barely technical matters *per se* but rather constitute complex issues of human relatedness. Nevertheless, the attractiveness of technological fixes as offering reliable risk mitigation and reassurance in the safety of biotechnology is ever growing. It suffices to mention that the H5N1 controversy discussed above was in part resolved after the lead researchers in the Netherlands and the USA respectively agreed to add a detailed section on the technical specificities and laboratory biosafety and



biosecurity measures taken during the experiments.<sup>65</sup> The strategy has proven effective in diverting attention from the rather inconvenient questions regarding the utility and significant potential for hostile misuse of the so called ‘gain-of-function’ (GOF) research and concentrating it on more mundane issues dealing with in-house precautions and safety procedures. Once the latter were deemed adequately resolved, the former were effectively forgotten.

Still, the value of technical means in ensuring reliable risk management should not be taken for granted. For one thing, laboratory biosafety precautions, however sophisticated, are far from perfect and accidents do occur. Such is the case with the Pirbright site in the UK which was at the centre of a major outbreak of foot-and-mouth disease in 2007, as a result of which over 2100 animals were slaughtered.<sup>66</sup> In 2012 the bioterrorism BSL-3 laboratory at the US CDC in Atlanta suffered repeated problems with airflow systems designed to help prevent the release of infectious agents.<sup>67</sup> The faulty system could perhaps be regarded as an exception had it not been for the authoritative investigation report of the US Government Accountability Office (GAO) released in March 2013. According to the report, the cost of building and maintaining high-containment laboratories, coupled with the absence of national standards for their design, construction, operation, and maintenance ‘exposes the nation to risk’.<sup>68</sup> Far more critical is the situation in the developing world and emerging economies where lax regulations and technical failures have significantly heightened the risk of accidental release of pathogens, as demonstrated by the numerous ‘escapes’ of the Severe Acute Respiratory Syndrome (SARS).<sup>69</sup>

But even if technology functions impeccably, this hardly reduces the likelihood for a human error or inappropriate behaviour. Unlocked doors in high-containment facilities hosting deadly pathogens, eating and drinking in laboratories and poor waste disposal practices are just a small part of the otherwise long list of mundane mishaps that may result in severe consequences. It is worth mentioning that the US CDC came under the spotlight after internal e-mail correspondence revealed that doors in the BSL-3 block where experiments involving the causative agents of anthrax, SARS and influenza were performed were left unlocked on numerous occasions, thus increasing the risk of unauthorised access or theft.<sup>70</sup> Given the chance of technical flaw and the potential for human error, some life scientists have begun to question the reliability of existing laboratory precautions and demand thorough review and evaluation. In a

recent letter to the European Commission the Foundation for Vaccine Research has asked for ‘a rigorous, comprehensive risk-benefit assessment’ of GOF research that ‘could help determine whether the unique risks posed by these sorts of experiments are balanced by unique public health benefits which could not be achieved by alternative, safe scientific approaches’.<sup>71</sup>

## ENGINES THAT DRIVE BIOTECHNOLOGY MOMENTUM

By and large, the ongoing progress of biotechnology is largely viewed and assessed through an explicitly positive lens which allows focusing almost exclusively on the benefits likely to be accrued notwithstanding the risks, actual and potential. The resultant distorted image is problematic, not least because it precludes any comprehensive discussion on the potential side effects and negative implications of novel life science advances. Above all, it sustains the barely questioned assumption that the existing governance mechanisms are adequate and sufficient to cope with the stresses and strains of the rapidly evolving biotechnology landscape. Yet given the complex and multifaceted dynamics shaping the life science enterprise, the rapid pace of innovation, and the limits to predicting the synergistic and cumulative effects of the proliferation of new technologies, the uncritical acceptance of such assumptions is at best naïve and at worst dangerous.

### *Integration of Biology with Other Disciplines*

Arguably the advancement of the life sciences has greatly benefited from the fascinating breakthroughs made in other areas of study, such as chemistry, engineering, computing, informatics, robotics, mathematics and physics. Some commentators even talk about a Third Revolution in Biotechnology underpinned by scientific and technological convergence:

Convergence does not simply involve a transfer of tools sets from one science to another; fundamentally different conceptual approaches from physical science and engineering are imported into biological research, while life science’s understanding of complex evolutionary systems is reciprocally influencing physical science and engineering. Convergence is the result of true intellectual cross-pollination.<sup>72</sup>

The resultant 'New Biology' has opened up a range of marvellous possibilities enabling the manipulation of living matter at the full range of scales, as well as the application of biological systems principles for the development of novel materials, processes and devices.<sup>73</sup> As such, it has been largely hailed as possessing the 'capacity to tackle a broad range of scientific and societal problems.'<sup>74</sup> This is not an exaggeration. As noted by a recent report of the US NAS, the precipitous decline in the cost of genome sequencing would not have been possible without a combination of engineering of equipment, robotics for automation, and chemistry and biochemistry to make the sequencing accurate.<sup>75</sup> Likewise, it is the combination of expertise from fields as diverse as evolutionary biology, computer science, mathematics, and statistics that has allowed both the analysis of raw genomic data and the subsequent use of these data to other fields.<sup>76</sup> At the same time, advances in nanoscience and nanotechnology have considerably enhanced drug delivery making it more accurate by targeting specific parts of the body.<sup>77</sup>

Yet the transformative potential of scientific and technological convergence comes at a price, not least because parallel to the benefits it offers, there are risks the effects of which could be truly devastating.<sup>78</sup> Take drug delivery, for instance. Thanks to the technological breakthroughs over the past decade, doctors have gained unprecedented access to the human body which, in turn, has facilitated the treatment of previously incurable disease and conditions (e.g. some forms of cancer). Nanoparticles and aerosols are now utilised for delivering a precise dose of therapeutics to tissues and cells via novel pathways circumventing body's natural defences and evading immune response. It is not difficult to imagine how such knowledge could be misapplied for malicious ends, including incapacitating and killing. Research on bioregulators is a case in point. Bioregulators are natural chemicals in the human body that play a vital role in the maintenance of the homeostasis but when administered in large quantities or in healthy individuals could be toxic and lead to serious disorders, even death. Given their properties, bioregulators constitute the perfect bioweapon: efficient and virtually impossible to detect. And if in the past, security analysts discounted the risk of their weaponisation due to the instability of the compounds when released in the atmosphere, the emergence of novel drug delivery techniques has significantly altered the security calculus.<sup>79</sup> This is just but one example of the challenges that the increasing convergence between biology and chemistry poses to the integrity of the international biological and chemical non-proliferation regimes.<sup>80</sup> Even

though some effort has been made over the recent years to address those and other areas of concern and strengthen the international prohibition against biological and chemical warfare, in practical terms little has been achieved, as a result of which the risk of the hostile exploitation of novel scientific developments remains far from hypothetical.

Along with the risk of misuse of new knowledge, there is the risk posed by the lack of sufficient scientific knowledge. Cross-disciplinary convergence opens a multitude of opportunities for manipulation and modification of living matter but, at the same time, it precludes almost any sensible assessment of the potential interactions likely to occur in the process. Nano-based medicine is but one area that has attracted criticism in this regard. Since some elements behave differently at nano-scale, it becomes extremely difficult to assess their level of toxicity or other negative side effects that they may exert. Such is the case with long carbon nanotubes, which having been initially praised for their potential to improve implant development<sup>81</sup> were later blamed for exhibiting asbestos-like behaviour that could lead to cancer.<sup>82</sup>

Another area of converging science with far-reaching implications is synthetic biology, a cross-disciplinary field that draws upon strategies and techniques from molecular biology, chemistry, engineering, genomics, and nanotechnology and thus enables the design and modification of biological systems at a fundamental level. Empowered by the tools of synthetic biology, in 2002 scientists managed to assemble a polio virus 'from scratch' in the absence of a natural template. And in 2010 Craig Venter and his team announced the construction of the first self-replicating synthetic cell which, in their view, was 'a proof of the principle that genomes can be designed in the computer, chemically made in the laboratory and transplanted into a recipient cell to produce a new self-replicating cell controlled only by the synthetic genome.'<sup>83</sup> The controversial work has attracted criticism on several grounds, including the potential negative effects of the accidental or deliberate release of the novel organism in the environment and the arrogance of scientists to 'play God'.<sup>84</sup> More broadly, both the polio and synthetic cell studies have exposed the obstacles to the regulation of synthetic biology.<sup>85</sup> While some commentators dismiss the risk of bioterrorism, underscoring the key role of tacit skills and knowledge and the difficulties that the lack thereof poses to the replication of the experiments,<sup>86</sup> other issues still merit attention. Consider the question of access to commercially available genomic sequences. Even though the oversight system for screening base pair orders has improved since the

2006 *Guardian* report that exposed the lax regulations under which virtually anyone could order gene sequences,<sup>87</sup> gaps still remain leaving scope for abuse by those with malign intent. For example, Schmidt and Giersch have outlined at least three areas of emerging challenges that the existing governance regimes would struggle to accommodate, including ‘split orders’, ‘outsourcing’, and the potential for non-natural biological systems.<sup>88</sup>

### *Biology as a Predictive rather than Descriptive Science*

The Human Genome Project completed in 2003 lasted over ten years and cost close to 3 billion dollars; by contrast, about a decade later, whole-genome sequencing can be performed within hours at a price of roughly 1000 dollars or less.<sup>89</sup> While still in its infancy, personalised medicine and individual genetic testing are steadily gaining popularity. Indeed, ‘up to 100 000 people in England are expected to have their entire genetic makeup mapped in the first stage of an ambitious public health programme’ launched by the National Health Service in 2012 that aims to ‘revolutionise the treatment and prevention of cancer and other disease.’<sup>90</sup> According to its proponents, genomic testing offers numerous advantages *vis-à-vis* traditional evidence-based medicine, including the possibility of early diagnostics of disease, of individually-tailored treatment and, perhaps most importantly, of disease prevention, as illustrated in the resolve of the Hollywood actress Angelina Jolie to undergo double mastectomy after discovering she has an inherited genetic mutation that puts her at high risk of breast and ovarian cancer.<sup>91</sup> But this is just the beginning. In 2012 scientists managed to sequence a foetus’s entire genome using a blood sample from the mother and a saliva specimen from the father, a development that could potentially allow for a range of genetic disease conditions to be detected prenatally.<sup>92</sup> And laboratory experiments have already demonstrated the efficacy of genetic therapy to cure mitochondrial disease by creating an embryo with genetic material from both parents and a third person acting as a donor.<sup>93</sup>

While truly breathtaking, the advances outlined above raise a host of thorny issues of ethical, social, and legal concern that merit public scrutiny and extensive deliberation before decisions regarding their widespread application are made. At a very basic level, there is the question of whether and to what extent we as individuals are capable of assimilating the information that our own genetic makeup may reveal. Are we sufficiently

resilient to cope with the emotional distress, anxiety, shame, stigma and guilt that the awareness of severe medical conditions that we or our closed ones are suffering or likely to develop? Far from hypothetical, this question has prompted the establishment of a novel profession, that of the genetics counsellor whose task is to help patients overcome any negative effects, stress, or psychological trauma that the disclosure of their genomic map may create.<sup>94</sup> This is just a partial solution though, for the crux of the matter lies in finding a way to deal effectively with risk and probabilities and we as humans are yet to demonstrate a capacity for understanding or relating them to our own lives.<sup>95</sup>

Individual emotional turmoil, however significant, constitutes only the tip of the iceberg. According to Daniel Kevles, the torrent of new genetic information has already begun to fundamentally reconfigure social practices and inter-personal relations:

It has been rightly emphasised that employers and medical or life insurers may seek to learn the genetic profiles of, respectively, prospective employees or clients. Employers might wish to identify workers likely to contract disorders that allegedly affect job performance while both employers and insurers might wish to identify people likely to fall victim to diseases that result in costly medical or disability payouts. Whatever the purpose, such genetic identification would brand people with what an American union official has called a life-long ‘genetic scarlet letter’ or what some Europeans term a ‘genetic passport’.<sup>96</sup>

Linking genetic makeup with human identity would ultimately set the scene for the proliferation of technologies aimed at human enhancement: after all, if a gene therapy could allow one to stand a chance in a job competition, boosting one’s capabilities would potentially make them a more desirable candidate. Other issues of more immediate concern are also likely to arise. One is privacy. Gene-sequencing companies usually hold the genetic data of their clients in digital format on online platforms, which automatically creates a risk that personal information may be leaked, hacked or stolen.<sup>97</sup> Further, there is the question of ownership. Consider, for instance, the controversial issue of human gene patenting, whereby patented genes are treated as research tools and, as such, are controlled by the patent holder who may restrict and charge for their use.<sup>98</sup> Thus created, the system often operates to the detriment of patients by hindering research practice, elevating

diagnostics prices and denying access to second and independent medical opinion.<sup>99</sup> Gene identification alone has a potential ‘dark side’ too, for it could enable the development of weapons targeted at group-specific gene markers (e.g. ethnicity).<sup>100</sup>

Pre-natal genetic testing is yet another significant bone of contention, not least because it evokes notions of state-mandated eugenic programmes and assaults on human rights and dignity. While a Nazi-like campaign for a superior race seems improbable in the twentieth-first century, this is not to say that other forms of eugenics may not be encouraged. Indeed, some commentators have highlighted the rise of ‘homemade eugenics’,<sup>101</sup> whereby individual families can make decisions on the attributes of their progeny:

The lure of biologically improving the human race, having tantalised brilliant scientists in the past, could equally seduce them in the future, even though the expression of the imperatives may differ in language and sophistication. Objective, socially unprejudiced knowledge is not *ipso facto* inconsistent with eugenic goals of some type. Such knowledge may, indeed, assist in seeking them, especially in the consumer-oriented, commercially driven enterprise of contemporary biomedicine.<sup>102</sup>

It is plausible to assume that when presented with the opportunity of having their future child tested for genetic disorders, many parents would barely hesitate to accept. Such a resolve could have far-reaching implications though. For instance, some genetic therapies entail the use of donor DNA different from that of the parents, whereby any genetic modifications in the embryo will pass down to future generations.<sup>103</sup> Despite the government support for the ‘three-parent babies’ in the UK, local religious organisations have protested vociferously against the legalisation of the technique.<sup>104</sup> At the same time, there are certain genetic disorders that can be diagnosed at an early stage but, as of yet, cannot be cured, which inevitably poses the tough choice between raising an unhealthy child and abortion. To be sure, such questions constitute more than individual parents’ dilemmas, for they touch upon established social and cultural values, something evident in the profound differences across national reproductive policies. More broadly, there are concerns that reproductive genomics may remain a prerogative of those affluent enough to afford it, thus further exacerbating the divide between the global rich and the global poor.<sup>105</sup>

*Diffusion of Life Science Expertise: International Collaboration,  
De-Skilling and Amateur Biology*

The growth of life science capacity over the past few decades across the globe has been truly astonishing, leading to the emergence of a vibrant research community that brings together researchers from various parts of the world. Indeed, a 2011 NAS report highlights the extension of both North-South and South-South partnerships, which has played a key role in synergising strengths and maximising competitiveness by improving the quality and effectiveness of research and facilitating data sharing.<sup>106</sup> At the same time, increasing collaboration in the realm of biotechnology industry has offered companies situated in emerging economies access to the global market, thus contributing to economic development and growth.<sup>107</sup>

Recent advances in technology and laboratory and experimental equipment have further impacted on the practice of life science research in profound ways. Improvements in DNA sequencing technology have significantly shortened the time required for the preparation of nucleic base-lines, thus relieving scientists of the burden of completing the task themselves and allowing them to focus on their actual project instead. Studies and experiments once performed by senior researchers with extensive experience are now carried out by Masters students. Aided by specially designed genetic engineering toolkits, children as young as the age of ten start exploring the realm of biology in an interactive and engaging manner. Needless to say, their notion of science and the world in general would differ significantly from that of their parents whose primary sources of knowledge used to be textbooks and encyclopaedias. Indeed, the increasing commercialisation of synthetic biology offers anyone curious enough to fiddle with biological systems the chance of doing so in the comfort of their own home.<sup>108</sup> Such modern gene hackers often lack formal background in biology and come from various walks of life. Driven by an insatiable appetite for knowledge and the vision of a ground-breaking discovery that could be turned into a multi-million dollar profit, they take up the rather unusual hobby of biohacking which entails the redesign of existing and the creation of novel biological systems. For just few hundred dollars bio enthusiasts set up laboratories easily obtaining all essential requisites and equipment from online sales. And if to some biohacking equates to little more than an unusual hobby, others highlight its potential to generate substantial revenue and fuel economic development.<sup>109</sup>



Contrary to popular expectation, biohackers are not just eccentric individuals who work in solitude away from public attention. Rather, they are members of a wide global movement dedicated to the ideal of Do-It-Yourself Biology (DIY), which has branches in 45 locations on four continents.<sup>110</sup> The movement has been partially institutionalised through the establishment of the BioBricks<sup>111</sup> and International Genetically Engineered Machine (iGEM) Foundations, which seek to promote the open and ethical conduct of biological engineering and stimulate innovation and creativity. To this end, iGEM holds an annual competition open to high school students, university undergraduates and entrepreneurs from all over the world. With more than 200 participating teams, the competition constitutes the premiere forum at which biohackers can showcase their skills through project presentation.

Exciting as it may seem, the ongoing diffusion of life science expertise poses an array of governance conundrums. At the level of professional practice, the proliferation of research facilities around the world has exposed the urgent need for laboratory biosafety and biosecurity training, especially in developing states where a tradition of handling dangerous pathogens is lacking. The issue is further complicated, for such countries often lack the required legal and institutional infrastructure to ensure that professional practice is in compliance with relevant international regulations. Foreign aid has gone some way in helping overcome those deficiencies but it has given rise to new problems, too. For instance, it is far from unlikely for a donor state to provide material support for the construction of a state-of-the-art laboratory eventually leaving its maintenance to the local government, which can hardly afford the subsequent costs. A similar trend is observed in the area of capacity building and human resource development. Most projects that aim to promote biorisk management and a biological security culture tend to be severely constrained in terms of time and funding and overly ambitious in terms of agenda and expected outcomes. Lack of adequate mechanisms for quality assessment hinders progress evaluation and sometimes leads to duplication of effort and resources.

The emergence of the DIY biologists in the life science arena has further added to the challenge of ensuring that novel scientific and technological developments are utilised in a safe and ethical manner. Even at the level of everyday practice, difficulties still persist. For instance, many amateur scientists have complained of the lack of manuals and guidelines regarding the safe operation and maintenance of home laboratories. Issues such as waste disposal, safe handling and storage of biological material and

prevention of contamination pervade the work of biohackers who unlike professional researchers conduct experiments in a much more volatile environment.<sup>112</sup> Potential security concerns are also present. With more and more individuals gaining access to biological engineering technologies, ensuring appropriate oversight of what goes on in garage laboratories becomes increasingly difficult. The experience of the US FBI is a case in point. Back in 2004 the FBI arrested Steven Kurtz, a professor at the University of Buffalo under the suspicion of plotting a bioterrorist attack.<sup>113</sup> The subsequent investigation revealed that all laboratory and DNA extraction equipment found in Kurtz's house was legitimately obtained and used in his artwork. In an attempt to avoid mistakes of this kind, the FBI has drastically changed its approach to dealing with the DIY movement launching a series of outreach activities that seek to raise awareness of the potential security implications of biohacking.<sup>114</sup> While undoubtedly necessary, such initiatives may well be seen as too little, too late in light of the wide spread of materials, tools and devices that could facilitate the malign misuse of the life sciences. Indeed, it is worth noting that as early as the late 1990s the US Defence Threat Reduction Agency (DTRA) managed to build a research facility that simulated the manufacture of weaponised anthrax using only commercially available materials and equipment.<sup>115</sup>

### *The Role of States: Both a Poacher and Gamekeeper*

Structural factors have an important bearing on the development and growth of biotechnology. Economic considerations, power interests and realist fears generate potent dynamics that shape and influence and sometimes direct the life science trajectory. Within this context, states assume a dual role. On the one hand, they are expected to act as gamekeepers and regulate, monitor and control the process of life science research and the dissemination of novel technologies. On the other hand, though, they also have powerful incentives to act as 'poachers', not least because of the fascinating opportunities for enhancing their prosperity, prestige and security that scientific and technological development open up.<sup>116</sup> The following passage effectively outlines states' dual function:

Government has an important role in setting long-term priorities and in making sure a national environment exists in which beneficial innovations will be developed. There must be a free and rational debate about the ethical

and social aspects of potential uses of technology, and government must provide an arena for these debates that is most conducive to results that benefit humans. At the same time, government must ensure economic conditions that facilitate the rapid invention and deployment of beneficial technologies, thereby encouraging entrepreneurs and venture capitalists to promote innovation.<sup>117</sup>

Given that the agent (i.e. state governments) in charge of initiating ethical debates on the progress of biotechnology is also the one expected to provide the conditions that would allow this progress to generate outcomes likely to contribute to economic growth and political superiority, it is hardly surprising that any issues likely to slow down or otherwise hinder the enormous momentum of the life sciences are omitted from public discussion. This duality further informs how risks are perceived, framed and addressed. For instance, even though most of the developing countries lack capacity to manage dual use research of concern, they do not see this as an immediate priority and prefer to invest effort and resources in improving their laboratory biosafety and laboratory biosecurity infrastructure and capacity.<sup>118</sup> In the view of their governments, the dangers of naturally occurring and circulating diseases constitute a far greater worry than the potential for misuse of cutting-edge research. By contrast, some developed countries, most notably the USA, have embarked on building their biological defence systems highlighting the grave threat posed by the potential use of bioweapons by non-state actors. Their activities have encountered severe opprobrium as some analysts see them as a contraction of the norms embedded in the BTWC.<sup>119</sup>

The evolution of the chemical and biological non-proliferation regime epitomises the attempts of states to avert the hostile exploitation of the life sciences whilst promoting their use for 'peaceful, prophylactic and protective purposes'. The entry into force of the BTWC and the Chemical Weapons Convention (CWC) in 1975 and 1997, respectively, is indicative both of states' renunciation of chemical, biological, and toxin weapons and of their commitment to the goals of arms control and disarmament. That said, the imperfections and shortcomings of these treaties signify the influence of realist fears and political calculations that pervade international negotiations. In the case of the BTWC, two points merit attention. The first pertains to the lack of verification mechanism when the treaty was first agreed back in the early 1970s. Subsequent revelations of secret state-led offensive

biological programmes in the former Soviet Union, South Africa and Iraq up until the early 1990s have significantly undermined the Convention. Second, the failure to negotiate a binding protocol in 2001 has further dimmed the prospects for strengthening the regime and thus ensuring universal compliance with its prescriptions. Less acute but just as worrying is the situation regarding the CWC. Even though the Convention is exemplary in many respects, not least because of its verification system, almost universal membership and implementing body – Organisation for the Prohibition of Chemical Weapons (OPCW) – it still faces serious challenges that need to be considered. For instance, while the treaty bans the development, production, acquisition, and retention of chemical weapons, the definition of ‘purposes not prohibited under th[e] Convention’ entails ‘law enforcement including domestic riot control purposes’ (Article II.9d). Some commentators have argued that given the lack of a universally agreed definition what kind of activities count as ‘law enforcement’, this text opens a major loophole in the Convention.<sup>120</sup> Several States Parties of the Convention have voiced concerns in this regard. Australia has noted that:

The weaponisation of [Central Nervous System] acting chemicals for law enforcement purposes is of concern to Australia due to the health and safety risks and the possibility of their deliberate misuse, both of which have the potential to undermine the global norm against the use of toxic chemicals for purposes prohibited by the Convention. [...] Australia’s position is that it is not possible for a State Party to disseminate anaesthetics, sedatives or analgesics by aerial dispersion in an effective and safe manner for law enforcement purposes.<sup>121</sup>

Critics highlight the possibility for the deployment of novel chemical weapons for the purposes of countering terrorism, something evident in the 2002 Moscow theatre siege (Dubrovka) when the Russian security forces used a fentanyl-derivative agent, as a result of which about a sixth of the hostages and all of the terrorists involved died.<sup>122</sup> In 2011 the European Court of Human Rights ruled with regard to the Dubrovka operation that:

there had been no violation of Article 2 (right to life) of the European Convention on Human Rights concerning the decision to resolve the hostage crisis by force and use of gas.<sup>123</sup>

The Court, nonetheless, noted that:

Even if the gas had not been a ‘lethal force’ but rather a ‘non-lethal incapacitating weapon’, it had been dangerous and even potentially fatal for a weakened person [...].<sup>124</sup>

The Court further confirmed some of the earlier criticisms that were levelled against the Government, particularly in terms of preparedness and provision of medical assistance.<sup>125</sup> According to the ruling, Russia had to pay damages to all the 64 applicants – representatives of siege victims. To date, Russian officials have withheld information concerning the exact formula of the gas, which was used during the Dubrovka operation, on security grounds.<sup>126</sup> Given the lack of an internationally agreed definition of what constitutes ‘terrorism’ on the one hand, and the rise of irregular/asymmetric warfare and sporadic conflicts, on the other, some commentators have warned against the possibility of a ‘grey area’ which may enable states to utilise non-traditional methods of war to gain advantage.<sup>127</sup>

### *Speed Differential Between Scientific Advancement and the Pace of Deliberative Systems*

Deliberative systems encompass a vast array of practices, processes and mechanisms, both formal and informal, whereby a polity considers the ‘acceptability, appropriateness and control of novel developments in or impacting on, shared social and physical arenas’.<sup>128</sup> By design, they reflect and are informed by the values, beliefs and standards shared among the group, or in other words, by the prevalent culture. As such, deliberative systems vary across societies with their intensity, inclusiveness and structure depending on the established political and social norms. Yet their chief purpose and function remain virtually the same, namely to help societies adapt to the changing circumstance of their milieu in a way that ensures stability, sustainability and safety.

Public deliberation requires time; and wide-ranging life science advances, current and planned, offer profound challenges to shared ideas and ideals about the foundations of human relatedness and of social coherence, justice, human dignity and many other norms, both formal and informal.<sup>129</sup> Yet given the ruminative nature of deliberative processes, on the one hand, and the fast speed at which biotechnology

innovation is evolving on the other, the danger of the former being steadily outpaced and overburdened by the latter is far from hypothetical. Consider the following passage sketching the scale of social changes likely to arise from the increasing convergence between nanotechnology, biotechnology, cognitive neuroscience and information technology:

In the foreseeable future, we will be inundated with new inventions, new discoveries, new start-ups, and new entrepreneurs. These will create new goods and new services. [ . . . ] As expectations change, the process of politics and government will change. People's lives will be more complex and inevitably overwhelming. Keeping up with the changes that affect them and their loved ones exhausts most people. They focus most of their time and energy on tasks of everyday life. In the future, when they achieve success in their daily tasks, people will turn to the goods and services, the new job and investment opportunities, and the new ideas inherent in the entrepreneurial creativity of the Age of Transitions. No individual and no country will fully understand all of the changes as they occur or be able to adapt to them flawlessly during this time.<sup>130</sup>

This vision of a 'brave new world' merits attention on two important grounds. First, it implies that the changes likely to occur in the not too distant future as a result of the rapid progress of science and technology are imminent and unavoidable in the sense that their advent hardly depends on or even requires extensive public deliberation. Second, given that our capacity for adaptation to and grasp of those changes will be considerably impaired, the Age of Transitions leaves little space for public deliberation. To add to this gloomy picture, there is already some evidence that the progress in the life sciences is overwhelming the existing deliberative mechanisms. For instance, Kelle et al. argue that the rapidity of biotechnology advancement coupled with the immensity and complexity of the knowledge accumulated therefrom complicates efforts to deal with potential risks, something evident in the regulatory gap that the convergence of chemistry and biology has created in the area of arms control.<sup>131</sup> This is problematic, for the reduced resilience of deliberative systems provides favourable conditions in which scientific and technological innovation can continue unabated. A vicious circle is thus created in which the inability of deliberative systems to cope with the strain exerted by biotechnology advancement fuels the latter turning it into a self-propelling force.

The proliferation of contentious ‘gain-of-function’ research is a case in point. Even though the H5N1 controversy discussed in the preceding sections exposed the limitations of existing governance mechanisms for addressing the potential security, ethical, and legal implications arising from such studies, it hardly precluded scientists from conducting similar experiments. Indeed, less than four months after the moratorium on research involving contagious H5N1 virus was lifted, a team of Chinese researchers announced the creation of a hybrid of the H5N1 strain and the H1N1 virus that caused the 2009 flu pandemic.<sup>132</sup> And it was not long until the newly-emerged H7N9 influenza virus became airborne, as well.<sup>133</sup> If anything, those examples indicate that in light of the rapid pace of life science progress, addressing governance concerns on a case-by-case basis is not only self-defeating but given the number and variety of conundrums, it is likely to become unsustainable in the long run.

### RUNAWAY BIOTECHNOLOGY?

Given the significant potential of biotechnology to bring about multifaceted changes in different spheres of life and generate considerable benefits in the form of new products, enhancement of public and private capital and alleviation of social ills, there is a powerful urge to allow the ongoing expansion of the life sciences to proceed largely unfettered. Risks are carefully calculated and, where possible, downplayed as hypothetical at the expense of comprehensive deliberation. And even when proposals for risk mitigation measures are entertained, preference is usually given to those unlikely to hinder the progress of life sciences. By and large, there is a genuine belief that the existing governance mechanisms in the area of biotechnology can accommodate and cope with the wide-ranging pressures exerted by scientific innovation and the rapid diffusion of technologies with multiple uses, by offering ‘solutions’ and handling concerns on a case-by-case basis. In particular, the technology of safety is still ‘celebrated as an unadulterated improvement for society as a whole’.<sup>134</sup>

Yet there are reasons for scepticism toward the adequacy and effectiveness of the governance approaches currently in place. Much of the discussion in the preceding sections has focused on the ways in which the increasing pace, growth and global diffusion of biotechnology advances are beginning to expose the limits of the existing measures for control and risk management by challenging accepted values and beliefs and redefining established norms of practice. As the multifaceted dynamics driving the

biotechnology momentum continue to intensify and multiply, it becomes more and more difficult to comprehend, let alone foresee, the various impacts that the large-scale deployment and proliferation of novel scientific and technological advances have both on our social systems and the environment. Given the tight coupling between human-made and natural systems and their complex, often unanticipated interactions with catastrophic potential, the existing narrow definitions of risk are rendered inadequate.<sup>135</sup> At the same time, the advent of new technologies with multiple adaptive applications opens up an array of possibilities for hostile exploitation thus compelling governments to make tough decisions in an attempt to reconcile the benefits of biotechnology with the potential security concerns arising therefrom. While the advancement of biotechnology promises tremendous public health benefits, it also holds a considerable catastrophic potential, as the case of ‘gain-of-function’ experiments illustrate. As scientific capabilities and work involving dangerous pathogens proliferate globally, so do risks and the prospects of failures, whether technical or arising from human error. Indeed, assessing the rapidly evolving life science landscape some security commentators argue that ‘current genetic engineering technology and the practices of the community that sustains it have definitively displaced the potential threat of biological warfare beyond the risks posed by naturally occurring epidemics’<sup>136</sup>. Laboratories, however well equipped, do not exist in isolation but are an integral part of a larger ecological system. As such, they constitute a ‘buffer zone’ between the activities carried out inside and the wider environment. And despite being technically advanced and designed to ensure safety, this ‘buffer zone’, just as other safety systems is far from infallible. For one thing, mechanical controls leave room for human error and personal judgement, both of which are factors that could be highly consequential but which could hardly be modelled or predicted with exact certainty.<sup>137</sup>

The speed at which the transformation of the life sciences is taking place is yet another factor that adds to the complexity of life science governance. Stability is a fundamental condition for the development and preservation of human and natural systems alike. In social systems, culture is the primary source of stability, for it determines what values, beliefs, practices and modes of behaviour are deemed acceptable and, as such, lays the foundations of order. All forms of governance therefore are cultural artefacts and manifestations of culture. Culture also provides the tacit standards whereby change is assessed and treated as acceptable or unacceptable. Hence, any state of affairs in which the



rate of change precludes regulation disrupts the ordinary functioning of the system and jeopardises its preservation:

The breakdown of human regulation does not extinguish regulation of a simpler sort. [...] The system formed by men and the rest of the natural world will continue to regulate itself after a fashion, even if human regulation wholly fails at all levels above the primary group. But the resulting 'order' would exclude all those levels of human order which man-made stability makes possible.<sup>138</sup>

To be sure, a world characterised by a runaway biotechnology would be far different from the one we know. The main challenge to averting this prospect lies in ensuring that the systems of governance are in sync with the progress of life sciences. History has shown that even highly developed, long-standing systems of governance can fail for reasons as diverse as disasters; loss of authority/legitimacy of governing bodies; and pervasive corruption. One further source of failure includes the inability of a society to adapt to its changing milieu:

Men are adaptable; they can learn to live even in harsh and hostile environments – so long as the environment remains constant enough to give them time to learn. [...] If they form the habit of adapting by constantly changing that to which they are trying to adapt, they build uncertainty into the very structure of their lives. They institutionalise cluelessness.<sup>139</sup>

The process of adaptation is closely connected to cultural patterns and any serious disruptions in the latter could have detrimental effects and impair it severely. The extent to which change is taking place within the framework of the prevalent culture defines the borderline between system evolution and system disintegration. The governance mechanisms currently in place, both formal and informal, are all a function of historical, cultural, and socio-political contingencies. As such, their capacity for adaptation largely depends on our ability to comprehend and assimilate the complex changes that the progress of biotechnology brings about. They can only evolve as fast as our shared standards, values, routines and perceptions allow them to. And that is why governance can hardly be reduced to a technocratic exercise; on the contrary, to be effective, it requires extensive deliberation and full appreciation of the far-reaching implications of novel life science advances.

## NOTES

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