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ASIAN BIOTECHNOLOGY AND DEVELOPMENT REVIEW

Special Issue on Bioeconomy for the Common Good

Editorial Introduction

Articles

What Do the British and Chinese Governing Visions on Human Genomic Research Tell Us about Biosovereignty?

Joy Y. Zhang

Conceptual Tools for the Analysis of Bioeconomic Fairness and Efficiency

Tom Douglass

Perpetual War and Peripheral Peace? Commentary on the Historical Drivers of (Bio)Technology in the US and in Brazil

Érico Sant'Anna Perrella

Combating the 'Silent Crisis' of the Donation Gap with 'Polyphonic Relatedness'

Jill Shepherd and Joy Y Zhang

Centella asiatica Complex Health Tea: Opportunities and Challenges

Yanfei Geng

Application of CRISPR-Cas in Ageing and Health Equity

Chengxu Long and Wei Yang

Wisdom of Inclusion for a Fairer Global Bioeconomy

Di Zhang

Building Responsible Life Sciences in Africa: Observations from an Early-Career Female Scientist

Janet Surum

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Editorial Introduction

Bioeconomy for the Common Good: A Myth, A Sham or An Inspiration?

Joy Y. Zhang* and Krishna Ravi Srinivas**

Bioeconomy, or the use of biotechnology and biological resources to provide information, products, processes and services to all economic sectors, is key to various global and local concerns. The past years witnessed a significant development in bioeconomy strategies globally: In October 2021, the World BioEconomy Forum, a global platform for sharing ideas on bio-based responsible innovations to promote circular bioeconomy, was for the first time hosted by a Global South country, Brazil. The Forum also concluded with the Brazilian Governor of the Pará State launching Brazil's first dedicated biostrategy (World BioEconomy Forum, 2021). A few months later, in May 2022, China launched its first ever national five-year plan on bioeconomy, with the ambition of raising the value of the sector to 22 trillion yuan (\$3.3 trillion) (Ouyang, 2022). In the UK, in addition to its Innovation Strategy and Genome UK implementation plan, its Human Fertilisation and Embryology Authority continues to 'future proof' its legislations (DSIT and DBEIS, 2021; Office for Life Sciences et al, 2021, Devlin, 2022). In September 2022, President Biden signed the Executive Order on Advancing Biotechnology and Biomanufacturing Innovation (White House, 2022). In April 2023, India's Department of Biotechnology (DBT) released its 'Bioeconomy Report 2022' report (BIRAC, 2022), envisioning bioeconomy's contribution to the GDP will leap from current 2.6% to almost 5% by 2030.

However, with the emerging norms of research organisation, changing geopolitical dynamics, new natural and societal challenges and shifting public values, the conceptualisation and practice of bioeconomy itself is also evolving. The special issue brings together empirical and conceptual investigations on what a fair, efficient and vibrant bioeconomy (may) look like, and on how we could collectively promote it for social and planetary well-being.

We found paradoxes that are created or accentuated by new technical realities. Biosovereignty, for example, was a regulatory outlook that was once celebrated as a resistance to the biocoloniality of power. But, as Joy Zhang's comparative analysis shows, as the role of data evolves in bioscientific development, the assertion of a narrowly-defined biosovereignty may further harm the public benefits in late developing countries. She demonstrates a

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‘precariousness in biosovereignty’, as a result of often ignored fact that power-imbalances and political hegemonies also exist within a nation-state and that not all voices are equally recognised as part of a national collective.

The socio-political nuance within a nation-state and its importance to releasing the full potential of a bio economy is further discussion in Jill and Zhang’s article on the UK’s ‘silent crisis’. That is, a persistent barrier to mobilise non-White communities into actively contributing to and, subsequently benefit from structural and scientific advantages that the UK biobanks and bio-databases can offer. Building on their ongoing research on stem cell donations, they argue that the building of a ‘polyphonic relatedness’, or a thick societal relatedness could help mitigate racial disparity in biomaterial donations. Participation and health equity is also highlighted by Long and Yang. They present a contradiction in which the latest progress in CRISPR-Cas technology opens up new possibilities for addressing health problems related to aging, but individuals from marginalized older populations face barriers in accessing this technology. For them, how to establish and sustain a trustworthy inclusive user participation scheme is a challenge that governments yet to find satisfactory answers to.

There are also chronic conundrums. Long, Waldstein, Wu and Geng’s account on the modern scientific validation on the health benefits of *Centella asiatica* as a tea beverage reminds us of the fraught history of the role indigenous ethnobotanical knowledge played in modern science and the lingering question if a equitable and sustainable path can be taken in translating ethnobotanical knowledge into marketable products.

Another example is Africa’s lagging behind the world in science and technology capacity. Janet Surum’s perspective piece underscores the complexities of harnessing life sciences for the common good. While progress is evident, the challenges of infrastructure, economic disparities, translational research, and the balance between commercialization and public welfare remain pertinent. These challenges are not new. But communities in African countries are not passive either, they are actively experimenting new solutions. For example, Surum shares her experience at the Mawazo Institute in Nairobi, a Kenyan non-government organisation that transforms African science by empowering female researchers. Her article provides unique account on the under-explored value of humanizing science and making it accessible to a broader audience to inspire the next generation of African scientists.

Empirical dilemmas are also venues where conceptual tools can be tested, our socio-technical outlook adapted, and governing alliances and strategies established anew. Tom Douglass’ paper illustrates how regulatory procedures can paradoxically function in ways that primarily favor the pharmaceutical industry, ultimately detrimenting patient and public health. By focusing on three crucial ideas – pharmaceuticalisation, corporate bias,

and the permissive principle – as formulated and employed by Abraham, Douglass argues that they together offer new tools for social researchers to unravel the potential detrimental effects of the industry’s sway, connections, and vested interests on the bioeconomic balance and effectiveness. While his analysis is primarily oriented in the UK context, the discussion was aimed to invite global reflections, extensions and corrections.

In a similar fashion, Di Zhang, a bioethicist at the Chinese Academy of Medical Science, updates the old Chinese wisdom of achieving multi-facet inclusivity and diversity, Jian Rong Bing Bao, with contemporary insights. Arguably, one of the ironies of our time is that while concerns like climate risks, heritable genome editing, and pandemics emphasise a shared future and the importance of safeguarding the common good, we simultaneously inhabit an ideologically divided world, where a distinction between “Us” and “Them” appears to be gaining renewed prominence. Through examining how inward reflections and outward engagement are and can be manifested in contemporary science politics at the national and international level, Di Zhang calls for a more empathetic and prudent balancing acts of science governance.

But how realistic is Jian Rong Bing Bao in global realpolitik? Di Zhang is frank about China’s own struggle with this principle. Érico Sant’Anna Perrella’s short comparative piece on the role of militarisation in biotechnology’s development in Brazil and in the US is itself an expression of anxiety (and perhaps also an ambivalence) from the Global South. Reading in connection with other articles in this issue, Perrella’s piece raises some unsettling and important questions about how positionally and developmental pathways feed into each other.

As a special issue, we do not aim to be exhaustive or conclusive. We can only provide snapshots of some of the views and deliberations that are taking place in different regions. We made an effort in inviting early career researchers (especially those based in the Global South) with experience in policy debates to share their views. What type of cultural-political confidence is needed to recognise what constitute ‘good’? Can diverse interests be ‘commoned’ into a coherent good without evoking an imagined Other (or worse, an enemy)? To what extent is our perception of bioeconomy for the common good shaped by historical legacies? Is the pursuance of common good a myth, a sham or an inspiration for the upcoming generation? We hope the readers can approach this issue as a provocation, an invitation, and as a documentation, which feeds into your own conclusion of the above questions.

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What Do the British and Chinese Governing Visions on Human Genomic Research Tell Us about Biosovereignty?

Joy Y. Zhang*

Abstract: Genomic research lies at the core of national bioeconomies and is a strategic area for national scientific competitiveness. Drawing on the UK's latest national vision on genomic research and my participation in one of China's policy consultations on its implementing rules on human genetic resources, this paper demonstrates how China's conception of 'biosovereignty' may be counterproductive, both to its scientific competitiveness and to the health of its people. The key argument is that 'biosovereignty' is not a property of an individual, a community, or an institution. Rather it is a powerful assemblage of ideals, infrastructures and network of capitals that steers our collective future. It is simultaneously a social contract and a social construct, both of which are evolving with socio-technical realities. The paper provokes reflections on the role of the state in promoting equitable genomic research and the question on what 'biosovereignty' means and how it should be represented.

Keywords: China, CRISPR genome editing, ethics, genomics

Introduction

With the discovery of the sequencing technique of DNA in the 1970s, the world has witnessed a fast-evolving genomic revolution. Yet with anticipated applications in precision medicine, population genetics, virus surveillance breakthrough of diagnosis, prevention and treatment, it seems that scientists, investors and the public alike are only at the beginning of grasping genomic research's full potential (Green et al, 2020; Neufeld, 2021; Mills 2022). Genomic research lies at the core of national bioeconomies and is a strategic area for national scientific competitiveness. The past few years saw the launch of national strategies for genomic research, such as the France Genomic Medicine Plan 2025, Germany's genomeDE strategy (2019), Genome UK (2020), and EU's 1+ Million Genomes initiative (2020). However, human genomic research has also been Western-centric, both in terms of the focus of its study (e.g. 86% of existing genomics studies are focused on people of European descent) and in terms of its professional power dynamic (Schwartz-Marín and Restrepo, 2013; Xiong, 2021; Fatumo et al, 2022).

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China presents a unique case. On the one hand, similar to many developing countries, bioprospecting and exploitative medical research remains a not-so-distant memory for Chinese society (Keim, 2003; Xiong, 2021). On the other hand, China is one of the few Global South countries that has the capacity and resources to reshape global genomic research. Following its first formal national legislation on human genetic resources in 2019 (State Council, 2019), China's *Biosecurity Law* promulgated in October 2020 further elevated the importance of human genetic resource governance as a matter of national security. Article 53 of the *Biosecurity Law* further claimed the governance of human genetic resources as part of China's national sovereignty (Standing Committee of the National People's Congress, 2020). This 'biosovereignty' framing, along with its securitisation of human genetic data, has generated much debate (Mallapaty, 2022; Sharma, 2022). More importantly, as this paper argues, China's decolonial invocation of biosovereignty may paradoxically alienate Chinese bioscience from global genetic research and thus reinforce a colonial power disparity. This is more evident when juxtaposing it with the global trend towards democratic governance over data-sharing (Fatumo et al, 2022; Hilberg, 2022).

Drawing on my familiarity with the UK's latest national vision on genomic research and my participation in one of China's policy consultations on its implementing rules on human genetic resources, this paper demonstrates how China's conception of 'biosovereignty' may be counterproductive, both to its scientific competitiveness and to the health of its people. The key argument is that 'biosovereignty' is not a property of an individual, a community, or an institution. Rather it is a powerful assemblage of ideals, infrastructures and network of capitals that steers our collective future. It is simultaneously a social contract and a social construct, both of which are evolving with socio-technical realities. The paper provokes reflections on the role of the state in promoting equitable genomic research and the question on what 'biosovereignty' means and how it should be represented.

Biosovereignty as a Modern Concept

Sovereignty is one of those core concepts whose meaning seems to be apparent to all while simultaneously being hard to pin down. For precisely because of its centrality to socio-political life, its meaning evolves and multiplies. For example, despite China's recent emphasis on biosovereignty, its definition seems to be taken for granted, as Chinese laws have not considered it necessary to give a specific definition. However, in this paper, sovereignty refers to the authority of a state in modern politics which is exercised through representative bodies, rather than the power of a monarchy (such as the British Crown) (Philpott, 2020). Broadly defined, the global

conception of biosovereignty can be traced to the UN's 1993 adoption of the Convention on Biological Diversity (CBD). Article 3 of the convention stipulates that 'states have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction'. In other words, while the Convention is premised on the recognition that the conservation of biodiversity is a common concern of humankind, it also affirms the right to control genetic resources and associated traditional knowledge as part of 'national sovereignty'. It must be noted that the Convention on Biological Diversity is primarily an instrument for environmental protection, thus human genetic resources is not covered by the Convention. In the mid-2000s, Indonesia was at the epicentre of an avian influenza outbreak. Samples collected from patients were initially sent to international laboratories affiliated with the World Health Organization's Global Influenza Surveillance Network (GISN). However, after detecting that some pharmaceutical companies in developed countries were profiteering from these specimens by developing treatments and vaccines which developing countries may not be able to afford, the then Indonesian Health Minister Siti Fadilah Supari announced that the viruses isolated from within Indonesian jurisdiction as sovereign property and refused further sample sharing. While since this controversy, sovereign rights were extended to viral genetic resources, there remains no explicit global agreement on ownership regimes over human genetic resources (Rhodes, 2016; Hong, 2018).

However, it is safe to say that CBD forms the foundations of the modern conception of biosovereignty. In relation to the discussion of this paper, there are two features that I want to highlight. One, the primary aim of asserting sovereignty was to ensure 'fair and equitable sharing of the benefits arising out of the utilization of genetic resources' (CBD Article 01). The assertion of biosovereignty is to counteract what Juan Camilo Cajigas termed as the 'biocoloniality of power', an exploitation of genetic resources under Western-dominant capitalist logic (Cajigas 2007 in Schwartz-Marín and Restrepo, 2013, p. 994). As such, the proposition of sovereignty over genetic resources is to promote common prosperity. It is not intrinsically against the usage of biomaterials or against its global exchange. Rather it underlines the recognition that how genetic resources are used has a significant consequence for the public good. Knowledge and biomaterial flow from the Global South to the Global North are not necessarily controversial or exploitative, but there has always been a struggle of 'epistemological advocacy' in the matrix of global geopolitics (Hayden, 2003, p. 31; Hilberg,

2022). For example, Cori Hayden's ethnography in Mexico demonstrates, bioprospecting, the 'distinctly late-twentieth-century practice' in which corporate interests exploit biomaterial or traditional knowledge from less-developed biodiversity-rich regions, originally received moderate support from some Mexican ethnobotanists, chemists, and pharmacologists. This is because these local professionals considered 'the project of "translating" traditional or folk medicine into chemical compounds as a mode of advocacy itself' and is 'instrumental to the production of the "credibility" of (and now, dividends for) traditional knowledge' (Hayden, 2003, p. 32). It was only when multinational corporations turned such knowledge translation into a lucrative industry that a wave of exploitation was ushered in (Fredriksson, 2021). Thus, sovereignty claims in the modern age particularly resonate with decolonisation projects, which recognise the right to self-determination of all people (Williams, 2007, p. 6 original emphasis).

Relatedly, a second point that I want to draw attention to is the fact that national 'sovereignty' over genetic resources, or biosovereignty, was not conceived as an exclusive entitlement to usage or benefits, but a prerogative to set the terms of accessing biological resources within their jurisdiction. To put it in another way, sovereignty over genetic resources is constructed both as a sovereign right (i.e. the authority over resources) and as a sovereign duty (i.e. to act in the interest of the people) (Cotula, 2018). As biomedical science has become a data-intensive science (Dunn and Bourne, 2017; Altman and Levitt, 2018), the governance of human genetic resources is also related to a more general issue of data sovereignty, which, echoing the definition of biosovereignty, refers to 'the control of data flows via national jurisdiction' (Hummel et al, 2021, p. 1). In fact, in relation to genomic research, data access and data sharing at scale are critical to generate clinical meaning and verifying hypotheses (McGuire et al, 2021). 'Harvesting data then not making good use of them is not morally neutral' and does not constitute a trustworthy stewardship (Horton and Lucassen, 2022, p. 5)

Sovereignty is not absolute autonomy in the absence of external interferences or domestic conflicts. In fact, sovereignty is always contextual. It is conditioned by international relations and by domestic infrastructure (Williams, 2007; Hummel et al, 2021). More importantly, it is also conditioned by meaningful negotiation and collaboration between multiple agents who may have reasonable claims to data sovereignty (Fredriksson, 2021; Hummel et al, 2021; Hilberg, 2022). While not all countries have explicitly claimed national sovereignty in human genetic resources, all countries have exercised de facto biosovereignty through their biogovernance regimes on biomedical research, clinical application and biobanking. In the sections below, I analyse current governance regimes on human genomes in the UK and in China. Particular attention will be

given to the different national outlooks on how human genetic resources and associated data should be shared and how its governing conditions can be met.

Genome UK: Seizing the Future By Facilitating Access

In September 2020, the UK released the long-term plan Genome UK: The Future of Health Care, setting out the blueprint for the next decade of genetic research in the UK. The long-term plan underlined the importance of tapping into the innovative power of social enterprise, strengthening collaboration between public and private bodies, and facilitating the translation of genome data into clinical applications. Genome UK is to enable the vision of ‘mak[ing] the UK the best location globally to start and scale new genomics healthcare companies and innovations’ (Department of Health and Social Care, 2020, p. 56).

The most prominent aspect of Genome UK is that widening data access and enhancing the usage of the UK’s genomic datasets are key to future global competitiveness. It is a nationwide effort that involves incentivising engagement from the scientific community and also from the general public. Not only is ‘readily accessible and well curated’ datasets to researchers recognised as ‘necessary to maximise the benefits of research’, but also patients and the public were ensured ‘access to their own genomic and health information and [to] have an appropriate voice in the use of their data for research’ (Department of Health and Social Care, 2020, 12, 31). Furthermore, an easily accessible high quality genomic dataset is seen as a way to reinforce UK’s global presence and influence. UK Biobank provides ‘non-preferential access’ to researchers in different countries, undertaking health-related research that is for the public good (Department of Health and Social Care, 2020, p. 36). In fact, as of 2020, UK Biobank has approved over 12,000 registrations from researchers based in over 1,500 institutes in 68 countries (Department of Health and Social Care, 2020, p. 36). In fact, 80% of data access applications it receives come from outside the UK (www.ukbiobank.ac.uk).

The socio-economic rationale behind ‘mak[ing] the UK the best place in the world to access genomic data for research’ is not difficult to comprehend (Department of Health and Social Care, 2020, p. 7). In addition to taking advantage of its well-curated database to attract financial and intellectual capital globally, if the UK’s genomic dataset becomes the core of the world’s cutting-edge life sciences, then the British people will naturally be the most direct beneficiaries of the subsequent medical knowledge and clinical application. It will also help to establish a new norm where ‘new genomics-based treatments to be sold globally from a UK base’ (Department of Health and Social Care et al, 2022, p. 58).

The visions embedded in Genome UK highlighted a radical transformation in how ‘value’ is identified and realised in genomic materials. It is a good example of a paradigm change in how bioeconomy policies are conceived. For example, a conventional impression is that it is a common practice for Global North researchers to outsource clinical trials to Global South communities for advantages such as cutting costs, speedy recruitment and weak overseas governance structure (see Cooper, 2008; Kamat, 2014; Spielman, 2015). However, in 2020, the UK was already one of the top three bases for early clinical trials of cell therapy and gene therapy in the world. Although the UK has only 0.87% of the world’s population, it hosts 12% of the above-mentioned early clinical trial treatments in the world (Department of Health and Social Care et al, 2022). It is worth noting that while UK Biobank is a world-leading database with comprehensive data of 500,000 volunteer participants, 89% of the participants are from England. If its data are used as the blueprint for scientific research and innovation, the direct beneficiaries of future biomedical innovations are self-evident. Moreover, the UK also hopes to further expand its share in the world in order to become a genetic diagnosis and treatment for both common and rare diseases innovation base. The strategy was to ‘support a 50% increase in the number of clinical trials over the next five years ‘with a particular focus on ‘grow[ing] the proportion of “change of practice’ trials and trials with novel methodology over the next five years’ (Department of Health and Social Care et al, 2020, p. 43). The ambition was further reinforced by two subsequent policy papers: Genome UK: 2021 to 2022 Implementation Plan published in May 2021, and Genome UK: Shared Commitments for UK-Wide Implementation 2022 to 2025 published in March 2022. In addition, the UK’s Department of Health and Social Security further released policy paper, Data Saves Lives: Reshaping Health and Social Care with Data in June 2022. The emphasis was not limited to expanding and diversifying datasets, but also on how to facilitate the sharing and circulation of biological information.

Genome UK and associated government policies strongly indicate that as biomedical research has become more akin to information science (Nakai, 2019), physical possession of biological material itself no longer constitutes scientific capital. For example, in 2020, the UK’s Parliamentary Office of Science and Technology’s briefing noted the rapid growth of the digital sequence information (DSI) of genetic resources has reduced the demand for physical genetic resources and new governance challenges and opportunities created by the disembodiment of property and knowledge (Parliamentary Office of Science and Technology, UK, 2020). In other words, the manifestation of biovalue becomes more reliant on its circulation and in its utility. The scope and frequency of a particular type of genetic

information is used critically to shape future medical knowledge, clinical norms and even priorities. Racial disparities in stem cell bank samples, for example, means that patients from Black, Asian and minority ethnic backgrounds have a significantly lower chance of finding a living-saving donors than patients with northern European backgrounds. Health inequality created by this data disparity was so immense that the issue is seen as ‘Silent Crisis’ in the UK (see Shepherd and Zhang in this issue). How a lack of female data has created serious limitations of medical knowledge with real-world health impact is not only well-acknowledged in the academia but is increasingly of public knowledge (see Jackson, 2019; Kadambi, 2021).

To be sure, the value of biological materials cells, genes, and tissues have never been purely limited to being in and of themselves. However, with emerging trends in biomedical research, ‘biovalue’ has taken on a much expanded and versatile form that is beyond data extraction and is embedded in how bio-information is interpreted, compared, synthesised, designed and generated.

The heightened strategic importance of sharing and circulation of data has accentuated rather than decreased the demand for competent exercise of biosovereignty. Balancing easy access with safeguard issues such as privacy rights, benefit sharing, genetic discrimination, and public concerns about biological surveillance called attention to the significance of having a corresponding governing capacity.

In comparison with China, there are two main themes of capacity building that are worth highlighting. One is the investment in ‘hardware’ innovation and upgrade. To maintain the security and fair use of biological information, in addition to the well-established access approval and ethics review procedures, the UK has also introduced new governing tools and structures. Most notable is the UK Health Data Research Alliance’s (2020) development of a TREs (Trusted Research Environment) platform since 2017 to enable barrier-free large-scale parallel sharing of health-related data. In simple terms, TREs provides a firewall-protected operating environment in which different scientific teams can conduct remote analysis of anonymised health information simultaneously. This helps to reduce the risk of data leaks or abuse. If a conventional logic of controlling biological information is to rely heavily on gatekeeping through user restriction, and requires tracking and responding to risks along the whole chain of data transmission (as exemplified by the Chinese rationale discussed in the next section), then TREs demonstrates an alternative ‘safe havens’ approach in which health data can be accessed and analysed in a secured environment monitored by the data provider (www.hdruk.ac.uk). The TREs model has its limits, such as it cannot be applied to the needs of ‘wet labs’, which requires access to physical biomaterials, not just informatised data. However, the

point here is that new data sharing imperatives demand not only regulations and guidelines dictating how data ‘should’ be used or by whom, but also require structural and technical support to enable safe and responsible data sharing and data processing. In other words, biosovereignty is not only a prerogative that needs to be recognised, but it embodies a systematic set of rights and responsibilities that need to be safeguarded through appropriate technical and structural support.

A second theme worth highlighting is the UK’s emphasis on cultivating public confidence and a sense of public partnership. Of the five governance themes stated in the implementation plan of Genome UK, the first two were on ‘ethics and maintaining trust’ and ‘engagement and dialogue with patients and the public’ (Department of Health and Social Care et al, 2022). Public access to their own data, their participation in related ethical debates and engagement efforts from the research communities are all seen as important to maintain public trust. Society’s exposure to both the potential benefits and potential negative impacts of genomic research is key for better societal understanding and support. The need to correct ethnic bias historically formed in most large genetic datasets through targeted minority recruitment was also recognised, although its challenge, as Shepherd and Zhang’s article in this volume demonstrates, still remains. But what is clear is an effort towards government-society partnership to further bolster the UK’s dominance as a global genetic data provider. In parallel, the nationwide project ‘Our Future Health’ was also launched. This project strives to expand the UK biological sampling scope through the collection of biomaterial and health information of millions of volunteers, in the hope of accelerating diagnostic and treatment discoveries (ourfuturehealth.org.uk).

At the time of writing, the Genome UK initiative still has another two years ahead. It is too early to assess its success or failure, especially given that Brexit and the COVID pandemic have introduced new scenarios into bioeconomy and bioresearch, not least in the UK but globally. However, it is safe to say that the new visions set out by the UK correspond to emerging norms of how biomaterial and related information are used in cutting-edge biomedical research and the new roles biodata play in defining new horizons of medical investigations. Would the rationale exemplified by Genome UK lead to new forms of biocoloniality in which new biomedical knowledge and innovations are effectively ‘enclosed’ by UK-based genome data? Only if there are few alternative datasets. National dominance aside, a more likely form of bio-disparity is the chronic problem of lack of racial diversity within a national dataset.

China: Securitising Data Access as Correction to Historical Injustice

Despite leading the world’s scientific output both by quantity and quality and being a major player in global genomic research (NISTEP, 2022),

China remains in a catching-up position when it comes to governing human genetic materials. It took two decades of deliberation before China established its current national regulation on human genetic resources in 2019. As demonstrated below, while there have been several rounds of nominal consultations, the making of the legislation appeared to be driven mostly by public servants with limited coordination with scientific, social and legal studies experts. As a result, the orientation of the regulations is mainly rooted in biopiracy and bioprospecting concerns, with minimal reflection on the changing roles of biomaterial and biodata in contemporary biomedical research and in bioeconomy. China remains overly reliant on punitive administrative measures that restrict data access. While its intention is to protect China-based innovation, its narrow understanding of biosovereignty has paradoxically become a new barrier for securing future research competitiveness and future health benefits for its population.

Similar to many other biodiverse countries in the Global South, such as Brazil, India and South Africa, China has long struggled to institutionalise effective rules on biopiracy and bioprospecting. China's earliest regulation was the 1998 Interim Measures for the Administration of Human Genetic Resources (hereafter Interim Measures) jointly promulgated by China's Ministry of Science and Technology and the Ministry of Health, in response to a series of exploitative Western medical research conducted in China in the 1990s, which came to be known as the 'Gene War of the Century' (Shou, 1997; Xiong, 2021). One most cited scandals concerned Harvard Professor Xiping Xu who led a local Chinese research team and collected tens of thousands of blood samples from illiterate peasants in Anhui province without proper informed consent (Keim, 2003). In the years to come, Chinese bioethicists often referred to this episode of exploitative bioprospecting as emblematic of the 'Wild West', a rebuttal to developed countries' 'Wild East' derision of China's early regulatory vacuum in the life sciences (Zhai et al, 2019). While the 1998 Interim Measures have set out general principles of promoting 'equal and mutually beneficial international collaborations and exchange' (article 1) and have mandated that only China-based partners can apply for government approvals on genetic data usage and sharing in international collaborations, the regulations were relatively sketchy. In the decades that followed, China's legislation over human genetic resources has moved slowly (see Table 1 for the list of key milestones). It was not until two decades later, in 2019, that the State Council (China's highest executive body) approved the *Regulation of the People's Republic of China on the Administration of Human Genetic Resources*. It took another three years for China's Ministry of Science and Technology (MOST) to publish *Detailed Implementing Rules for Regulation on Administration of Human Genetic Resources* (hereafter Detailed Implementing Rules) for public consultation.

Table 1: Summary of Key Milestones in China’s National Regulations on Human Genetic Resources

Year	Legislation
1998	Interim Measures for the Management of Human Genetic Resources
2005	Draft Regulations on the Management of Human Genetic Resources
2012	Regulations on the Management of Human Genetic Resources (Draft for Public Comment)
2019	Regulation of the People’s Republic of China on the Administration of Human Genetic Resources
2022	Detailed Implementing Rules for Regulation on Administration of Human Genetic Resources (Draft for Public Comment)

Source: Author on Compilation

According to a report produced by Deloitte, between 2016 and 2020, while the number of international studies with a China component and corresponding human genetic resource applications have steadily increased, the approval rate has steadily declined (Xie, Qian and Dong, 2021). The *Detailed Implementing Rules* publicised by the Ministry of Science and Technology in 2022 was widely regarded as China’s further tightening its control over the sharing and usage of genetic data (Mallapaty, 2022). China’s nationalist paper *Global Times* (2022) interpreted this as an effective ‘ban’ on using Chinese human genetic resources abroad. This is because *Detailed Implementing Rules* stipulates that only Chinese research institutions can collect, store and process Chinese human genetic resources. Overseas organisations and individuals, including institutions in which foreign stakeholders have financial control or ‘major’ administrative influence (Article 12) are no longer allowed to collect or store Chinese human genetic resources.

In addition, the *Detailed Implementing Rules* have made more specific requirements in the filing and handling of data and set specific conditions for benefit sharing. While the original intention is to protect China’s biomedical research interest and secure Chinese researchers more

leverage in international collaborations, many researchers considered the new stipulations in fact restricts Chinese scientists' international outreach and disincentivise collaborations. For example, Shuhua Xu, a geneticist at Shanghai told *Nature* that the new requirement for 'security reviews' of datasets involving more than 500 samples is a relatively small number for genetic research (Mallapaty, 2022). In addition, applying for permission from MOST is complex and time-consuming with no clear criteria publicised. It also significantly restricted Chinese scientists' capacity to deposit genetic data on global publicly accessible repositories, and their desire to join international research initiatives due to worries of a potential violation of this new data sharing legislation (Sharma, 2022).

The perverse effect of China's recent regulations on human genetic resources is mainly rooted in two inter-related issues. One is Chinese policy-makers' lack of engagement with the research community and society in general. The other is an over-fixation of a historical loss to biopiracy, which has blinded Chinese regulators from recognising the changing landscape of global biomedical research. I explain both points in turn through my policy consultation experience.

In April 2022, I had the privilege of being the only foreign national among the 22 experts invited to a policy consultation on the *Detailed Implementing Rules*, co-organised by Huazhong University of Science and Technology, the host of two main national major research projects on life science governance, and by the Bioethics Expert Committee of the Chinese Society for Dialectics of Nature. The panel consists of academics from the fields of bioethics, philosophy, law, sociology, stem cell research, cancer research and biobanking. The outcome was a 40 pages of recommended revisions (Lei et al, 2022). In the meeting, I proposed eight specific recommendations, evolving around promoting accountable data sharing internationally and establishing better government-society partnership to boost public confidence and public support. These were all included in the recommended revisions (Lei et al, 2022).

In contrast to Genome UK's comprehensive agenda of engaging with the public and mobilising their interest and participation, the *Detailed Implementing Rules* resembled more of a top-down government-led gatekeeping. The very limited input from wider scientific or legal communities in the drafting of the *Detailed Implementing Rules* was also reflected in its wording: a number of the scientific terminologies used were quickly identified as inaccurate or too general to be operational by the panel (Lei et al, 2022, 36). There were also a few places where legal experts pointed out a lack of precision or a conflict with other regulations. There was no mention of public access to their health data, nor an indication of involvement of professional associations or social enterprise (Lei et al,

2022, 5-8, 17-18). Another striking absence is a commitment to research infrastructure upgrades. Article 19 on ‘information system building’ was mainly on building a reporting system where it facilitates administrative tasks ‘such as registration, administrative approval and record creation’. Article 20 on ‘foundational platform and databank building’ is mainly focused on standardisation and professionalisation of biobanks, with no guidance on data management, such as internet security, cross-institution sharing, etc.

It seems the primary consideration of *Detailed Implementing Rules* was not about better management of bio-data or bio-material per se, but about concentrating powers to manage people. Chinese authorities seem to consider ‘biosovereignty’ as a ‘thing’ that could be preserved by limiting contact. They fail to see ‘biosovereignty’ as a bundle of rights and prerogatives whose actualisation necessitates corresponding technical support, as well as the coordination of and contribution from various stakeholders at multiple levels. Relatedly, safeguarding biosovereignty was effectively reduced to guarding against foreign access and to economic calculations of benefit sharing. *Detailed Implementing Rules* was more successful in mapping out a vision of administrative surveillance carried out by (national level) authorities than a vision on the future of biomedical research.

Legal experts at the consultation pointed out that the *Detailed Implementing Rules* had an imbalanced emphasis on punitive measures for wrongful sharing, at the cost of overlooking specifying the service or training that regulatory institutions can provide to enable and facilitate consistent compliance (Lei et al, 2022, p. 37). In fact, almost 1/3 of Chapter 6 of the *Detailed Implementing Rules* was focused on penalties. This debilitating effect of red tape around the access and circulation of data was raised by both scientists and social scientists. In the meeting I pointed out that current draft rules indicate an ethos of ‘safekeeping’ of genetic resources rather than responsible usage of them. A number of panelists echoed my view that biovalue is embedded in the frequency of biomaterials and bioinformation being put to use and in the scope of their circulations. Directors of regional biobanks in China were particularly worried that the safekeeping ethos would further aggravate the segregation of local biobanks, which are already battling with low willingness for data sharing, duplication of investments and low sample utilities which all negate a key function of human genetic biobanks which is to serve the needs of health research (Lei et al, 2022, p. 37).

Perhaps a more telling example of Chinese regulators’ lagging behind the contemporary research landscape was the mandatory benefit sharing clause, which generated much controversy among scientists and industry practitioners in China. It is useful to be reminded that, as noted at the beginning of this section, China’s regulation on human genetic resources

was reactionary to the ‘Gene War of the Century’. China’s policy gap left its society exposed to biopiracy and bioprospecting was a recent memory. Consistent with various interim measures and the eventual 2019 national legislation, there was an evident post-colonial sentiment in the Detailed Implementing Rules’ articles on mandatory benefit sharing.

For example, Article 16 of *Detailed Implementing Rules* dictates that any patent rights as a result of research based on Chinese human genetic resources should be co-owned by Chinese and foreign collaborators. Article 17 further stated that when benefit sharing with international collaborators cannot be agreed upon on the basis of research contributions, the benefits should be ‘equally’ split between Chinese and non-Chinese partners. While both articles were to give Chinese researchers legal backing to their negotiation with foreign counterparts, scientists at the consultation meeting noted that such clauses oversimplified the complexity of research collaborations, in which interests are often much more diverse and entangled than intellectual property rights or immediate economic benefits. Anecdotally, one legal scholar also pointed to examples where Chinese research teams would not honour the mandated benefit sharing with collaborators in other developing countries. Explicit mandates of an absolute equal split (such as Article 17) would not protect Chinese scientists’ interests but only isolate them from the global human genetics community, a view also expressed through media (see Mallapaty, 2022).

At the time of writing, China has yet to publish revised *Detailed Implementing Rules* following its public consultation period. Similar to many other non-Western countries, China was also once a victim of biopiracy and bioprospecting. Thus, a national human genetic resource regulation was a much anticipated legislation that could defend the Chinese scientific community and its society from future injustice. It was expected to promote a bioeconomy not for the few but for the common good. However, the practice and norms of biomedical research have drastically changed over the past few decades. China’s 2019 and 2022 legislation on human genetic resources raise an interesting pair of questions for the nation-states: Can the protection of biosovereignty be delivered through administrative decisions and be detached from the state of bioscientific research? Conversely, policy makers also need to consider to what extent is enabling national bioscientific research capacity a constitutive element of conducting biosovereignty, and whether that capacity-building can be restricted by a ‘nationalist’ lens.

Given the interruption caused by the COVID pandemic, the full effects of these new regulations on the global presence of Chinese biomedical science and global studies on Chinese human genetic data are yet to be seen. As researchers and biomedical enterprises both inside and outside of China have shown concerns over the impact of China’s restriction over data sharing, it may not be far-fetched to ask: Would Chinese authorities’

efforts to correct historical injustice over issues of narrow biosovereignty paradoxically create a secondary epistemic injustice for Chinese life science communities?

Biosovereignty Reconsidered

Sovereignty is a slippery concept, for it ‘is a mingled compound of idea, reality and goals’ that is subject to continuous ‘modification arising from changing goals or changing factual requirements’ (Lee, 2009). Biosovereignty, which incorporates both the sovereign authorities over genetic materials (e.g. genetic sovereignty) and related information (e.g. data sovereignty), is and should always be a concept-in-the-making, defined contextually and contingent to socio-technical changes. However, recent British and Chinese national regulations on human genomic resources remain informative on how biosovereignty could and should be conceived.

Firstly, biosovereignty is not a property or a privilege reserved for the state. At its core, sovereignty is a ‘supreme authority within a territory’ (Philpott, 2020). Yet as both the UK and China cases have shown, the realm of genetic research is where geopolitical, epistemic, economic, cultural and personal priorities intersect and overlap. The supreme authority within one territory may unavoidably compete or be in conflict with the authority of another (e.g. the need to align individual authority over their personal data with biobank’s authority over data usage, or China’s authority over data sharing was seen as in potential conflict with scientists’ authority over where to publish). This reinforces rather than contradicts Hobbes’ (1651) point in *Leviathan* that sovereignty is a social contract built on the consensus of the governed.

Secondly, expanding on the above point, biosovereignty, as an aggregated authority from an assembly of territories (or social spheres), represents a fundamental balance of consensus. This is why having diverse publics involved and continuously seeking their confidence and support matters in national visions of genomic research. This is also why human genetic regulations oblivious of myriad societal power relations would generate concerns and would resemble more of a practice of autocracy than an exercise of biosovereignty.

China’s invocation of sovereignty over human genetic materials recalls the Global South’s struggle against the biocoloniality of power. However, China’s 2019 Regulation and associated 2022 Detailed Implementing Rules seem to weaken Chinese human genetic research community’s global influence and dim the prospect of public health benefits. In contrast, by overturning the logic of data possession to data circulation, the UK seems to be enroute to secure future financial and health advantages by capitalising on its genomic data.

An assertion of biosovereignty was originally conceived as a way to counterbalance the colonial legacy of a West-Rest power dynamic. This also helps us to comprehend what, countries such as China and Indonesia are really demanding when they invoke the language of ‘biosovereignty’: At its core, the struggle for biosovereignty is about securing a nation’s collective self-determination over the use of biomaterials and over the development and application of associated science and technology. However, power-imbalances and political hegemonies also exist within a nation-state. Not all voices are equally recognised as part of a national collective. Thus, exercising biosovereignty may not necessarily be an act of epistemological advocacy. It is perhaps more accurate to say that biosovereignty, as an assemblage of ideals, infrastructures and network of capitals, could challenge, alter or reinforce existing political or epistemic hegemonies. This precariousness in biosovereignty’s effect lies in the fact that it requires a simultaneous assumption of a right and a duty: the right to set the conditions for the use of biomaterials and associated data, and the duty to ensure that those conditions are intelligible and sensible to the political audience. It also lies in the fact that biosovereignty itself is not static, but its meaning is contingent, primarily upon the evolving and expanding roles genetic materials play in biomedical science and upon the role of biomedical science in society.

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Conceptual Tools for the Analysis of Bioeconomic Fairness and Efficiency

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Abstract: This paper discusses three concepts from medical sociology – pharmaceuticalisation, corporate bias and the permissive principle – showing how these conceptual tools can be used to analyse bioeconomic fairness and efficiency in relation to the development, regulation and consumption of pharmaceuticals. The three concepts reveal the problematic impacts of the influence and interests of the pharmaceutical industry at various levels of the development, regulation and subsequent use of pharmaceuticals – and, as such, various possible examples of bioeconomic inefficiency and unfairness. First, the paper discusses the concept of pharmaceuticalisation which enables analysis of the social forces that can shape the new or widening usages of pharmaceuticals. It suggests that if social forces, such as medicalisation, consumerism or deregulatory ideology are driving the widening or new use of pharmaceuticals then pharmaceuticals in specific contexts might be said to be inefficient solutions. Next, the paper shows how the concept of corporate bias enables analysts to engage with the question of the interests served in pharmaceutical development and regulation. The paper highlights how, due to corporate bias, regulation can work unfairly in the interests primarily of the pharmaceutical industry and to the detriment of patient and public health. Finally, the paper discusses the permissive principle, where benefits are assumed to outweigh risks in pharmaceutical regulation. The presence of permissiveness means that pharmaceutical products that lack benefit or are unsafe may nevertheless achieve regulatory approval – potentially meaning inefficient spending or use of healthcare resources, as well as unfairly serving commercial interests over the patient and public health interests.

Keywords: Bioeconomy, pharmaceutical, regulation, medicalisation

Introduction

The pharmaceutical industry is a central actor in the current organisation of bioeconomy and pharmaceutical products are one of the key products emerging from biotechnology and bioscience. In the UK, in 2020, the value of the pharmaceutical industry was £40bn – the sector with the largest turnover in the UK life sciences sector (Office for Life Sciences, 2020). The dominant narrative, certainly in neoliberal capitalist societies, is that drug development is the process of developing and marketing pharmaceuticals for objectively identified health problems (Abraham, 2008a). Relatedly,

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large drug company profits are seen as the by-product of a job well done and are justifiable rewards reflecting risky financial investment in research and development. However, contrary to this narrative, a body of evidence (see Rodwin, 2013a) points to the potentially damaging influence and excessive reliance on the pharmaceutical industry across all dimensions of the development, regulation and consumption of pharmaceuticals (Rodwin, 2013b). Indeed, the pharmaceutical industry is central to the testing and production of medical knowledge about pharmaceuticals (Light et al., 2013), and they have developed intimate connections with ostensibly independent regulators and guideline developers who shape the prescription of pharmaceuticals by medical professionals (Cosgrove and Wheeler, 2013; Sismondo, 2013). In this regard, evidence suggests that vast financial incentives and the associated commercial interests of the pharmaceutical industry can negatively impact processes designed to ensure that pharmaceuticals that reach the market are safe, effective, beneficial and necessary with an associated fair and efficient use of resources.

This paper discusses three important concepts developed by and deployed in the scholarship of Abraham (1995, 2002, 2008a, 2009; 2010) that enable a social analysis of the biomedical narrative that pharmaceuticals are always necessary, beneficial solutions to objectively defined medical problems – particularly within psychosocial and lifestyle areas of medicine. As Abraham notes (see 2007: 41-42) pharmaceuticals may be lifesaving products but they can also cause serious adverse reactions in patients – and some drugs have minimal benefit, particularly in relation to existing alternatives (both pharmaceutical and non-pharmaceutical). Abraham's work encourages analysis of how social forces, relating particularly to the commercial influence and interests of the pharmaceutical industry may exaggerate, or even distort, the necessity and perceived utility of pharmaceutical products and result in the inefficient use of healthcare funding/resources when compared variously to other existing pharmaceutical products, non-pharmaceutical treatments or no intervention at all.

Considering the theme of this special issue, this paper argues that the concepts of pharmaceuticalisation, corporate bias and the notion of the permissive principle¹ emerging from decades of Abraham's scholarly output encourage and enable a crucial social analysis of the fairness and efficiency of the pharmaceutical sector as a significant branch of the bioeconomy nationally and comparatively.² Abraham's (1995; 2002; 2008a; 2010) work suggests that pharmaceuticals should be developed and regulated in a manner that provides people with products that they need without undue constraint whilst also ensuring that drugs are effective, safe, necessary and beneficial interventions. To do this pharmaceutical regulation should ensure that the use of state funding and resources in healthcare provision is not wasted on ineffective or dangerous products. In this regard, a healthy

bioeconomy should work fairly in the interests of patient and public health and not solely or primarily for commercial gain. The three concepts, in their own specific way, enable an analysis of whether bioeconomies are operating in this manner.

Abraham's body of work within the sociology of pharmaceuticals research area dates back three decades and is comprised of many journal papers and a range of books where he has analysed evidence of the problematic influence of the pharmaceutical industry on the growing consumption of pharmaceuticals – with his work attracting thousands of citations. Abraham's impact also stretches beyond academia. For example, he provided expert advice to the House of Commons Health Select Committee (2005) and published a report detailing the findings of a landmark investigation into the influence of the pharmaceutical industry on the growing use of pharmaceuticals and the associated disadvantages (including excessive medicalisation and seemingly growing rates of adverse events). In this regard, Abraham is a highly influential scholar analysing how the influences and interests of the pharmaceutical industry shape the nature and functioning of modern biomedicine whilst contributing to the associated attempts by the British government to understand the issue and ostensibly develop an effective policy response.

The primary contribution made in this paper is to act as an introduction to the work of Abraham's influential and vast body of scholarship. The three concepts explored in this paper are central to understanding Abraham's arguments – however, they emerge in different outputs and at different stages of Abraham's career. This paper aims to provide a streamlined introduction to and review of the most important dimensions of Abraham's scholarship, whilst asserting the utility of three of Abraham's conceptual tools in the analysis of the more general state of bioeconomic fairness and efficiency – and, in turn, encourage further empirical research drawing on his work. This paper now turns to explore in turn the analytic value that the concepts of pharmaceuticalisation, corporate bias and the permissive principle possess.

Pharmaceuticalisation

The first concept that can enable examination of bioeconomic fairness and efficiency is pharmaceuticalisation which is defined as “the process by which social, behavioural or bodily conditions are treated or deemed to be in need of treatment, with medical drugs by doctors or patients” (Abraham, 2010, p. 604). It is important to note that pharmaceuticalisation has a couple of different articulations by separate authors and to some degree is entangled or competes with the broader concepts of medicalisation and biomedicalisation which focus on more general issues beyond pharmaceuticals including the expansion of the (bio)medical realm. Some work suggests that there is no need for the newer concepts of biomedicalisation or pharmaceuticalisation

to be used alongside or instead of the older concept of medicalisation, rather than medicalisation can be updated to analyse new drivers of a widening medical realm, notably the pharmaceutical industry (Conrad, 2005). However, the specificity of pharmaceuticalisation arguably increases its analytic utility when examining the expanding usage of pharmaceuticals (which can occur without any new medicalisation) (see Douglass and Calnan, 2022a for a broader discussion). Abraham's conceptualisation of pharmaceuticalisation is centrally concerned with assessing the impacts and outcomes of pharmaceutical development, regulation and provision. He argues, in other words, that creating opportunities for new or widening uses of drugs can and should be assessed against whether (or not) it meets real, objective medical needs. In this regard, his approach is valuable for assessments of bioeconomic fairness and efficiency as it enables analysts to examine whether new pharmaceuticals or new uses of existing drugs are an objectively necessary use of funding/resources and relatedly beneficial for the patient and public health.

Abraham argues that to assess whether new pharmaceutical products or new applications of drugs are being fairly and efficiently developed, regulated and consumed they must be analysed against competing explanations. He argues that the increasing use of pharmaceuticals may be less well explained by the dominant biomedical narrative of meeting objective needs than by the social forces of medicalisation and industry promotion, consumerism, and deregulatory policies which may serve to create 'need'. In this regard, Abraham establishes the potential importance of sociological components fostering, particularly in some examples of psychosocial and lifestyle areas of medicine, "false claims and expectations about the capacity of pharmaceuticals to meet [health] needs" (2010, p. 617).

First, Abraham argues that medicalisation, which is the process of applying medical labels to social problems, may also be a better explanation than the dominant biomedical narrative for the widening availability and use of pharmaceuticals. For example, in the case of attention deficit hyperactivity disorder (ADHD) thresholds of what is considered 'normal' behaviour have been lowered so much that some studies suggested that 50% of all children could meet symptom criteria despite studies designed to identify the biochemical bases for ADHD suffering from problems of rigour and replicability, whilst the deviation of people diagnosed with ADHD from 'normal' levels of dopamine is contentious. Importantly, Abraham argues that the medical elites involved in defining or widening diagnostic categories are often associated with or funded by the pharmaceutical industry. In this regard, rather than pharmaceuticalisation reflecting the diagnosis of objective medical need, research and disease-awareness campaigns funded by industry may "have exaggerated the benefits of drugs, such as SSRIs, tranquillizers and Viagra, resulting in them being prescribed in ways that

have no techno-scientific basis” (Abraham, 2010, p. 609). Furthermore, Abraham shows that the pharmaceutical industry has also engaged in practices, such as ghost writing or editing scientific manuscripts to give the appearance of greater medical benefit, withholding negative data whilst also undermining critics and removing funding from institutions employing critical scholars. All of this is designed to uncritically result in the reframing of problems as requiring pharmaceutical treatment. This argument suggests that some new and widening diagnostic categories and the associated prescription of pharmaceuticals are not necessarily about the efficient meeting of objective health needs and instead reflective of the pharmaceutical industry’s influences on the evidence base – with the industry motivated by vast potential profits – as well as relationships with medical elites and professionals who interpret the evidence and prescribe drug treatments.

Next, Abraham shows how consumerism can be a driving force behind pharmaceuticalisation rather than the objective, efficient and fair meetings of need suggested by the dominant biomedical narrative. He identifies two types of consumerism. In simple terms, access-oriented consumerism (such as campaigning for access to new drugs) can drive pharmaceuticalisation, whilst injury-oriented consumerism (e.g. legal action taken due to harm caused by drugs) can limit or prevent pharmaceuticalisation. Though acknowledging the rise of the patient-consumer and consumerist principles within healthcare more generally, Abraham argues that access-oriented consumerism, where the interests of consumers align with the interests of the pharmaceutical industry, is likely to be much more successful than injury-oriented consumerism. In this regard, consumerism, though sometimes leading to de-pharmaceuticalisation, is more likely to support or drive pharmaceuticalisation. Indeed, Abraham discusses how consumer groups working in allegiance with or funded by the pharmaceutical industry to access pharmaceuticals with disputed evidence bases have often successfully pressed for access to expensive drugs funded through the NHS (see Abraham, 2009). This argument suggests that the influences and relationships of the pharmaceutical industry may result in a build-up of pressure that results in the possibly inefficient use of resources.

Abraham, finally, discusses the centrality of deregulatory ideology in driving pharmaceuticalisation. He notes that pharmaceutical product innovation has declined in the years that lifestyle and psychosocial areas have seen increasing pharmaceuticalisation. As such, the growing use of pharmaceuticals cannot necessarily be explained by growth in techno-scientific discovery/advance, or, as such, the dominant biomedical narrative. This decline in innovation is likely to be associated with de-regulatory tendencies within regulatory organisations from the 1980s onwards that have lessened the burden on the industry to be innovative, particularly because

new drugs do not have to show therapeutic advances over existing drugs. This is interesting because arguments by industry and those in government for lessening the regulatory standards have been rooted in claims that overwhelming regulatory burdens have restricted innovation. This argument suggests that deregulatory ideology is driving the development and use of some types of pharmaceuticals rather than the alternate thesis that objective need always leads to the new, efficient and fair utilisation of pharmaceutical products based on objective need.

Corporate Bias

The second concept that this paper argues can facilitate the examination of bioeconomic fairness and efficiency is corporate bias. Abraham (2008a) argues that at a

“particular time in pharmaceutical development and regulation there are techno-scientific regulatory standards, whose publicly declared purpose is to protect and promote public health by ensuring that drug products are adequately safe and efficacious. Methodologically, those standards can be deployed by sociologists to investigate how well, in practice, pharmaceutical testing and regulation act in the interests of public health, and how far they are influenced by commercial or other interests”

In this regard, he argues that there is evidence that patients and public health have real interests in medicines having an optimal benefit-risk ratio, whilst the pharmaceutical industry has an objective interest in the maximisation of their profits. Abraham argues, however, that pharmaceutical development and the regulation of pharmaceuticals, which ostensibly exists to protect public health, has sometimes failed to maximise the interests of patients and the public as a result of what he calls corporate bias. In this regard, this concept encourages analysis of the interests that are dominant in pharmaceutical development and regulation, and in this sense, how fair the process is for all interested parties.

The concept of corporate bias, which is based on an objective interest-driven framework against which action and behaviour can be analysed, suggests that

“the pharmaceutical industry was, and is, permitted to have privileged strategic access to, and involvement with, government regulatory policy over and above any other interest group; and more often than other factors, the industry was, and is, decisive in determining regulatory policy outcomes (or lack thereof). The

regulatory state and the pharmaceutical industry work largely in partnership and behind a cloak of secrecy.”

Bias, in this context, “is defined as a consistent trend or pattern of technical inconsistencies or contradictions mapped onto a set of social interests”. These technical inconsistencies or contradictions can mean that the techno-scientific standards of pharmaceutical development and regulation are biased by commercial interests away from the stated purpose of these standards which is to ensure drugs are safe and hold efficacy, and in the process, protect public health. This reflects, for example, the fact that drug regulators (such as the Medicines and Healthcare Products Regulatory Agency, the MHRA, in the UK, the European Medicines Agency, the EMA or the Food and Drug Administration, the FDA, in the US) are either partly or solely funded by fees they receive from pharmaceutical companies. To be clear, this means that pharmaceutical companies pay regulators to assess the efficacy, safety and quality of their products before marketing meaning in essence that pharmaceutical companies are customers of the regulators (see Calnan and Douglass, 2017 for a more detailed discussion of the processes of drug trialling and regulation; see also Calnan and Douglass, 2020; Douglass and Calnan, 2022b).

A programme of research by Abraham and colleagues has demonstrated the extent of corporate bias present in pharmaceutical regulation using historical and international comparative analyses. Indeed, bringing a new drug to the market is a costly exercise and the pharmaceutical industry has sought ways of decreasing costs and duration of development. In this regard, the industry has attempted to harmonise regulatory standards (which, to remind the reader, ensure that drugs are safe, of sufficient quality and hold efficacy) to access markets simultaneously and reduce the overall regulatory burden (Abraham, 2008a). Research has shown that the subsequent harmonisation that has occurred has ultimately led to decreased regulatory standards with fewer safety checks on new drugs resulting in quicker and less robust processes for bringing drugs to the market (Abraham and Reed, 2002; 2003). This is clearly to the benefit of the pharmaceutical industry but not necessarily patient and public health. This demonstrates how the pharmaceutical industry under the guise of greater efficiency has sought to make the development and regulation of pharmaceuticals less fair, rigorous and protective of patient and public health and to greater commercial benefit. It is here that value of the concept of corporate bias when analysing matters of the bioeconomy is clear as it reveals the corporate interests served by claims to regulatory ‘efficiency’ or regulatory developments/reforms claiming to increase ‘efficiency’.

Abraham (2009) additionally explores how corporate bias has shaped the ‘fourth hurdle’ of pharmaceutical regulation concerned with cost-

effectiveness (Timmins et al., 2016). In the UK, cost effectiveness evaluation of medical technologies including pharmaceuticals is conducted by the National Institute for Health and Care Excellence (NICE) rather than the MHRA (who, as noted, focus on the initial three regulatory ‘hurdles’ assessing the efficiency, safety and quality of pharmaceuticals). NICE conduct clinical and economic evaluations of whether pharmaceutical interventions can be justified based on expected costs over another intervention or decision to do nothing in terms of health impacts. In simple terms, they ask how well the treatment works in relation to how much it costs the NHS. Consistent with the problem of corporate bias, Abraham (2009) shows that NICE often only has access to published evidence (which, due to various industry practices, may have not always given the full picture). This has meant, for example, that SSRI antidepressants were initially considered appropriate for use in children based on the published evidence and thus accessible through the NHS. However, this was reversed when NICE gained access, in an uncommon occurrence, to the unpublished data. Abraham’s (2009) work here suggests that cost effectiveness regulation may not, as such, always lead to the efficient use of healthcare funding/resources under typical circumstances and may be biased away from working fairly in the interests of public health.

The permissive principle

Another important contribution in the work of Abraham and colleagues relevant to understanding bioeconomic fairness and efficiency is that of the use of the ‘permissive principle’ in the analysis of pharmaceutical development and regulation (Abraham, 2002; Abraham and Davis, 2009). The permissive principle is defined by the assumption that the benefits are said to outweigh risks of a pharmaceutical product unless substantial evidence of harm exists (Abraham, 2002, p. 20) and the “tendency to allow a drug on the market despite it not meeting established standards of efficacy or safety” (Abraham and Davis, 2009, p 570). The opposite and more traditional understanding of clinical trials and regulation, the precautionary principle, begins instead from the assumption that the regulatory standards are established because they are most able to assess the harm. In this regard, in applying critiques of permissiveness the burden of proof falls on those who argue new pharmaceutical products to be unsafe (Abraham, 2002). A precautionary approach is likely to require more considerable evidence of safety and benefit, particularly where alternate treatments might be available (Abraham, 2002).

Regulatory trust is an important component underpinning permissiveness. Abraham (2008b) outlines two forms or norms of regulatory trust known as investigative and acquiescent trust. The former is suggestive of trust relationships that result in a thorough assessment of evidence (and the

anticipation of this by industry), with the latter suggestive of trust relations that mean pharmaceutical industry data will be accepted relatively uncritically. Abraham suggests that in countries such as the UK and the US the underpinning norms of regulatory trust have shifted away from investigative towards acquiescent. This, Abraham suggests, reduces the incentives for the pharmaceutical industry to conduct adequate trials. Shifts in norms of regulatory trust are visible clearly in trends towards accelerated drug approvals as has been the case for cancer drugs in certain contexts (Davis and Abraham, 2011).

Evidence suggests that the permissive principle has featured in the regulation of pharmaceuticals over time (Abraham, 1995; Abraham and Sheppard, 1999) and often involves regulators violating their own established technical standards (Abraham and Davis, 2009). For example, in the case of triazolam (Halcion) a controversial hypnotic, in the US context in the 1990s, Abraham (2002) shows how the permissive principle functions. Anecdotal evidence (despite lack of compelling RCT data) was utilised to confirm efficacy by expert committees in the USA at the Food and Drug Administration (FDA) and the Institute of Medicine, whilst simultaneously RCT evidence was required to confirm a lack of safety. Selectiveness in the use and type of evidence here, to the approval benefit of the drug and pharmaceutical industry, is suggestive of permissiveness. Overall, if the benefit is assumed to outweigh the risk, with a heightened burden on attempting to disprove benefit over risk, and/or some undermining of a body's own technical standards, the permissive principle, as discussed by Abraham (2002) and Abraham and Davis (2009), can be said to have explanatory power. In this regard, if the permissive principle is shown to be present in regulatory activity, there will also likely be examples of inefficient uses of healthcare funding and resources occurring. Abraham's use of the permissive principle also suggests that regulation may not be working in the interests of patients and public health, for example, due to the violation of their own technical standards – and thus is operating unfairly.

Conclusion

This paper has outlined three important concepts – pharmaceuticalisation, corporate bias and the permissive principle – developed and utilised in the work of Abraham (1995, 2002; 2008a; 2010) that can be deployed to analyse the state of bioeconomic fairness and efficiency (both historically and in the present) as relates to the products developed and regulated in the pharmaceutical sector. It has been the purpose of this paper to assert the considerable value of Abraham's scholarship, examine and explain the utility of his conceptual apparatus and thus to encourage and enable further empirical analysis of bioeconomic fairness and efficiency. Though the focus

has primarily been conceptual, this paper has provided a range of examples of the ways in which Western, neoliberal bioeconomies have operated in an unfair and inefficient manner.

First, this paper has discussed the concept of pharmaceuticalisation which encourages analysis of the social forces that can explain the new or widening usages of pharmaceuticals rather than objective need and benefits for patients. If social forces, such as medicalisation, consumerism, or deregulatory ideology are driving the widening or new use of pharmaceuticals then specific pharmaceutical products might be said to be inefficient solutions. Next, the concept of corporate bias enables analysts to engage with the question of the interests served by pharmaceutical development and regulation – with Abraham suggesting that, due to corporate bias, it often works unfairly in the interests primarily of the pharmaceutical industry and to the detriment of patient and public health. Finally, the permissive principle, where benefits are assumed to outweigh risks, similarly enables analysis of the fairness and efficiency of regulation and thus the functioning of the bioeconomy. Rooted in acquiescent trust relationships between industry and regulators, the presence of permissiveness means that pharmaceutical products that lack benefit or are unsafe may nevertheless achieve regulatory approval – potentially meaning inefficient spending or use of healthcare resources, as well as unfairly benefiting commercial interests over patient and public health interests.

Other scholars working within the sociology of pharmaceuticals (see Douglass and Calnan, 2022 for an overview of this literature) have suggested that Abraham's realist approach – which centres analysis of necessity and interests – can lead to research that neglects the different values and patient choices associated with pharmaceutical consumption, whilst also suggesting that the importance of the roles played by patients and patient groups in pharmaceutical innovation and desire for new drugs may have been underappreciated in Abraham's work. This work additionally suggests that Abraham's approach to the analysis of pharmaceuticalisation may lead to an analytical neglect of the benefits and positives for patients and the bioeconomy (with similar criticisms made of older scholarship concerned with medicalisation – see Williams and Calnan, 1996). However, as this paper has demonstrated, analysis drawing on Abraham's three concepts' points to the problematic impacts of the influence and interests of the pharmaceutical industry at various levels of the development, regulation and subsequent use of pharmaceuticals – and, as such, various possible examples of bioeconomic inefficiency and unfairness in neoliberal societies. In this sense, there is clear value in the focus of and approach taken in Abraham's work.

In the years since the three concepts discussed in this paper emerged, there have been attempts to prevent or limit the extent to which the interests of the pharmaceutical industry can influence the development, regulation

and medical use of pharmaceuticals. This has occurred in relation to the implementation of more stringent ethical and regulatory requirements, including the need to register clinical trials and a growing emphasis on the importance of the disclosure of conflicts of interest by regulators, guideline developers and doctors (see Cosgrove and Wheeler, 2013 and Sismondo, 2013 for further discussion). Despite these positive steps, due to the control of and dependency on the pharmaceutical industry throughout the phases of drug development and regulation, it has proven difficult to radically reform the sector. It is also important to note that pharmaceuticalisation (particularly of psychosocial and lifestyle phenomena) continues to increase/widen. For example, in the UK in recent years already widely prescribed medicines taken by millions, such as statins (drugs used to lower cholesterol and reduce the risk of cardiovascular disease) have been offered to millions more people as a result of reanalysis of what is considered sufficient risk of developing cardiovascular disease (see Wise, 2014). It is true that in psychiatry, there is a growing critique of biomedical understandings of mental illness – such as a recent analysis that challenges the narrative of depression as caused by a ‘chemical imbalance’ (Moncrieff et al., 2022; see also Davies, 2021: 37-74). As this debate continues, social scientists could use Abraham’s concepts to usefully engage with, for example, the social driving forces of pharmaceuticalisation in psychiatry in the apparent absence of a biomedical abnormality that drugs like antidepressants can address.

Overall, the three concepts discussed in this paper are highly useful tools for social scientists to unpick how the industry’s influence, relationships and interests might harm bioeconomic efficiency and fairness in specific cases, in a range of regulatory contexts internationally, and comparatively. In this regard, social scientists drawing on Abraham’s scholarship can make a salient contribution to continued reform efforts and increased efficiency and fairness in the pharmaceutical sector.

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Endnotes

- ¹ The three concepts overlap and interlink in Abraham’s work – but this paper discusses them separately for the sake of clarity with the aim of delineating clearly how the concepts can be analytically deployed.
- ² The bulk of Abraham’s work has focused on the US, EU and UK contexts but the concepts can be used to analyse other neoliberal contexts.

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Perpetual War and Peripheral Peace? Commentary on the Historical Drivers of (Bio)Technology in the US and in Brazil

Érico Sant'Anna Perrella*

Abstract: This short commentary discusses the continuing role of war and militarism in the development of biotechnologies. I follow current and past events in the US related to the establishment of a formal structure - an intelligence community-led advanced research projects agency - where the military can interact with the market and act as an incubator and a consumer of new (bio)technologies. I contrast this traditional united-station approach with the current way the Brazilian Science, Technology and Innovation System is organized. The paper discusses the implications of these fundamentally different ways of producing (bio)technologies.

Keywords: Biotechnology, militarism, democratization, US, Brazil

US-Brazil political relations

*“In spite you
Tomorrow will be another day
I ask you where you will hide
From the enormous euphoria”¹*

From the samba “Apesar de você” from Chico Buarque

Brazil is a regional potency in Latin America and the 12th largest economy in the world.² The US is the second most important country in Brazilian foreign trade (Santander Website, 2023) and is the most economically, militarily and politically important country in the American continent. The US-Brazil relationship is an important part of Brazilian recent history: the 1964 military coup that established a brutal dictatorship was fully supported by the US government (Tavares, 2012); the Free Trade Agreement of the Americas guided most of the discussion in the 2000s as well as Brazilian dependency on huge International Monetary Fund and World Bank loans at the time. The main organizers of the popular campaign that ended in President Dilma Rousseff's impeachment (2014-2016), President Luis Inácio Lula da Silva's arrest and Bolsonaro's election in 2018, were proven to have strong ties with the US State Department and the US National Endowment for

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Democracy (Fang, 2017; Cristofolletti and Serafim, 2022). Brazilian foreign policy historians frequently use the figure of a pendulum to illustrate the way that Brazil interacts politically with the US (Milani, 2011). For times this pendulum steers closer to the US interests and for times it steers farther away. In democratic times, during Fernando Collor (1988-1992), Fernando Henrique Cardoso (1993-2002), Michel Temer (2016-2018) and Bolsonaro (2019-2022) presidencies, Brazil leaned closer to the US. During Workers Party governments - Lula (2003-2010, 2023-) and Dilma (2010-2016) - a certain distance was maintained from the US interests and policies. Studying these relations is a central part of contemporary Brazilian political sciences and correlated areas.

The US-led State-Industry-Academy Alliance

There is a wide discussion in the science and technology policy field about the role of war and defense spending in the creation of new technologies (Ruttan, 2006; De Landa, 1992; Galison, 1994). As technologies are embedded and intertwined in social structures, the way that they are created, disseminated and used, as well as by whom and for which purposes, are fundamental questions to be studied as they have a profound effect in shaping specific kinds of society and of sociality (Fortun & Schweber, 1993; Deleuze, 1992; Latour, 1988). The history of steel (Freeman & Soete, 2009; Landes, 1969), steam and internal combustion ships (Geels, 2002), the refrigerator (Mackenzie & Wajcman, 1985) and of the internet (Naughton, 2016; Ruttan, 2006), are but a few examples of technologies brewed in military settings or with military purposes that shape our contemporary occidental industrial lifestyle. Another recent trend that relates technology and specific forms of society is the emergence in the last century of the phenomenon of “big science” (Galison; Hevly, 1992). This way of doing science and technology is characterised by enormous projects that involve intense collaboration across three pillars of occidental contemporary political economy: the State, the industry and the academy.

The Project Manhattan (Kelly, 2005), Vannevar’s Bush 1945 “Science: the endless frontier” report to President Roosevelt (Bush, 2021) and the creation and operation of the DARPA (Defense Advanced Research Projects Agency) since the cold war (Bonvillian, 2013) are testimonies of how the military is a historically important piece in the American way of doing science and technology and of the State-industry-academy alliance. For all these projects to happen, the state and academy have to continually generate an inflow of qualified human resources - directed to the industry - capable of operating and designing ever more complex instruments, theories and machinery (Freeman; Soete, 2009, p. 30). The State, especially the defense sector, is also an important demand generator, funding the research

and development stages and buying the resulting technologies, products and services from these military-fostered innovation projects. (Mowery; Rosenberg, 1998, p. 123)

The United States was the first country to excel at this model of doing the same time both industry and science, exporting it to most European countries (Pavitt, 1998; Vonortas, 2000) and to some Asiatic countries like Japan, South Korea, and more recently China, Hong Kong and Taiwan (OCDE, 1992, p. 27; Yu et al., 2016), via the influence the US government and industry gained by means of hard and soft power. Key to this influence was both wars, the economic strength of US companies and the ideological pressure exerted by the various international organizations and forums led by the country's political elites such as the United Nations (UN), the International Monetary Fund (IMF), the World Bank, the Inter-American Development Bank (IDB), the Organization for Organisation for Economic Cooperation and Development (OECD) and the North Atlantic Treaty Organization (NATO). Data compiled from the financial results from the world's top 2000 companies shows that of the total of 25 sectors surveyed, in which 19 of them were US companies that regarded to be the most profitable in the world, especially in high-technology dependent sectors like telecommunications, computing, electronics, pharmaceuticals, aerospace and defense, oil and heavy machinery (Starrs, 2013). As research and development become routine in the life of any relevant company in terms of profits and of continuous improvement of products and services, the state-industry-academy alliance deepens.

The FELIX project from the US government Intelligence Advanced Research Projects Action (IARPA) is a recent and didactic example in the biotechnology sector of the US way of doing an applied industrial science and technology policy. Funded and coordinated by the IARPA agency and executed by the synthetic biology company Gingko Bioworks³ and former MIT laboratory Draper Lab, now a private entity, FELIX stands for Finding Engineering Linked Indicators and was a project executed between the years of 2020 and 2022, aimed at developing a dynamic molecular biology protocol, a device that could perform it automatically and a database of biological information that could act together to identify if a biological sample contained genetically engineered parts in its genome or not. In public presentations, the project was coined as part of an effort of the US government to biosurveil the world (IARPA, 2023), purposely with the intent of monitoring both the possible proliferation of biological weapons as well as to monitor intellectual property violations of US companies' patents by foreign companies and governments. IARPA is an agency linked to the Office of the Director of National Intelligence, a department created in 2005 to coordinate the various intelligence agencies of the US government.

IARPA follows the DARPA model (Bonvillion, 2013, p. 426) of success, characterised by short-term projects with clear goals, determined and managed by a team of experts both in the science and technology side but also in the military, industrial and commercial aspects of the projects. Each project is usually led by a distinguished researcher or practitioner in the field and this project manager is guaranteed access to everyone that matters in the US government structure, ensuring projects go forward without attrition and with maximum potentiality. IARPA was established in 2006 and functions under the direct supervision of the Director of National Intelligence, working with an undisclosed budget, a classified slice of the US\$89 billion annual budget to the intelligence community managed by the ODNI.⁴ According to its website, IARPA currently funds about ten projects, having funded at least 50 projects since the beginning of the agency's activities.⁵

The intelligence community, direct beneficiary of the technology resulting from IARPA's projects, is composed of 18 different organizations,⁶ two of them with full "department" status,⁷ nine are linked to the Department of Defense⁸ and seven are run by other US government departments.⁹ To work in any job within the intelligence community, one needs a security clearance ("confidential", "secret" and "top secret") and the process of obtaining it involves the need for a sponsoring organization and a comprehensive background check that will cover virtually every aspect of a candidate. As the process involves the sponsoring organization and takes up to a year from beginning to the end, most of the security credentials are given to people that come from the military service;¹⁰ the remaining credentials usually are given to people already working on non-classified jobs for private defense contractors, reflecting the increasingly privatized intelligence and defense environment.¹¹ As the intelligence sector history has strong ties to the military.¹² and a good portion of the people that work in the field come from military backgrounds, the Department of Defense - that directly controls 9 of the 18 intelligence agencies - and the US military holds tremendous influence in setting the priorities and practices of the intelligence community. Most officers and high-ranking people in the IC come either from the Department of Defense or from the Department of State, organizations focused on executing US foreign policy. In IARPA, the military-led intelligence community meets the market forces and mobilizes the academy to their advantage.

The technologies, products and services generated in this interchange will be privately provided to the US government by the companies that developed them - funded by the US government. If the market and the state agree that a technology is good enough to be used in any program and department inside the US government, the government usually buys the products and services related to it as part of congress authorized public

buying programs. In this way, the US government closes the loop between research and development and the actual deployment of technology. In some cases, such as the transistor (Lécuyer & Brock, 2010; Ruttan, 2006, p. 112) and the jet engine (Ruttan, 2006, p. 44), the state keeps buying products and services from companies at higher prices until the technology reaches maturity in terms of adoption and production costs.

Things are Different, for the Better and for theWorse

Despite Brazil being the 13th country in the addition of new papers in the platform Web of Science, the total Brazilian scientific production is pale in comparison to that of the United States: around 250.000 Brazilian articles against 2.500.000 united-statian in the 2011-2016 period (Clarivate Analytics, 2017). Brazilian-specific production of proprietary biotechnologies in turn is very weak outside agriculture, water treatment and production of food and beverages, with only a few hundred patent applications per year classified as biotechnologies (Vellani Júnior *et al.*, 2022). In comparison, US companies and institutions were granted around 6.000 patents in 2019 (Huggett and Paisner, 2020).

Not only the productivity level of the Brazilian science and technology is very different from the US, but the Brazilian innovation, science and technology structure is very different as well. In Brazil, the military and the defense spending does not have a fundamental role in the development of science, technology and innovation,¹³ except in a few areas directly related to the arms industry, that even with the military support are poor performers internationally (Carvalho *et al.*, 2021). The Science, Technology and Innovation (ST&I) system in Brazil is shaped after the Vannevar's Bush proposal for a national system dedicated to foster science and technology production (Cruz, 2011) but it is almost entirely composed of civilian public entities, most of them linked to the Brazilian Science and Technology Ministry (MCTI), to the Industry and Trade Ministry (MDIC) and to the ecosystem that encircles the Brazilian state-owned companies (De negri & Squeff, 2016) like BNDES (Banco Nacional de Desenvolvimento),¹⁴ PETROBRAS,¹⁵ Banco do Brasil,¹⁶ EMBRAPA¹⁷ (Empresa Brasileira de Pesquisa Agropecuária) and EMBRAER¹⁸ (Empresa Brasileira Aeroespacial). Despite being very important in national terms, for example, financing almost one hundred thousand research fellowships in Brazilian universities and research institutes (ASPUV, 2022), the Science and Technology Ministry is considered a weak department in terms of overall importance in the structure of the Brazilian government.¹⁹ Within Brazil, the states also have their own research financing agencies with varying degrees of importance, with the most populous states having financing agencies with more importance (SIBIUSP, 2018).

In terms of biotechnology research and development projects for

example, the Brazilian defense ministry currently (early 2023) has no public projects being funded or developed apart from maintaining one research institute dedicated to monitoring possible biological threats and to general biological research.²⁰ No other projects were found by the author being developed in any other arm of the Brazilian military structure or in the intelligence community. In comparison, EMBRAPA, a relatively small²¹ state-owned company dedicated to agricultural and livestock research, maintains dozens of different and independent research institutes around the country, generating production technology covering at least two dozen different plant and animal species.²²

In the opposite direction of the US model, Bolsonaro's government, composed mainly of military personnel, slashed drastically the funds for the Brazilian STI system and for the educational system during the last four years. The budget cuts made the universities during the Bolsonaro government to operate with around 50% of what they used to receive in funding from the previous governments (Dana, 2022).

As seen, in Brazil we do not have the military and defense spending as some of the main constituents of the science and technology production system, and this offers both a riddle and a glimpse of hope. The riddle is that in current geopolitics, having a strong industrial defense base and a blooming science and technology catalyzed by war and fear is an effective way of asserting and projecting national power, economically and politically. The perpetual state of war grants legitimacy to the constant procurement of new militarized technologies and this environment can incubate products and services that will be marketed and used both in military and civilian settings.²³ In this perspective, not having a strongly militarized big science structure is a profound national disadvantage, that condemns a country like Brazil to be a consumer of the technology generated by countries with strong enough states and militaries.

On the other hand, not having a militarized science and technology system means that the system will be guided with different perspectives on what is development and how to achieve it, maybe in more peaceful and understanding ways. What we crave in the periphery - and the Brazilian democratization process following the 25 years (1964-1988) of US-supported military dictatorship was characterized by a strong effort and desire to prevent military involvement in the national politics (Kinzo, 2001; Castro & D'Araujo, 2001) - is not a strong military state dedicated to catering to a very unequal world order problem, but rightly so, a strong and peaceful civilian state dedicated to solving pressing problems found in any third world city, from the calamitous persistence of hunger to the worrisome mental state of a ever-growing parcel of the population that find themselves trapped in low quality jobs and feel that their lives are meaningless, empty and hopeless.

Endnotes

- ¹ Translation from the original in portuguese: “Apesar de você / Amanhã há de ser outro dia / Eu pergunto a você onde vai se esconder / Da enorme euforia”. You can listen to Chico Buarques’s song with translations in english and spanish here: <<https://www.youtube.com/watch?v=4RhKTzVVDno>>
- ² Brazil oscillated in the last years from the 8th to the 12th largest economy (World Bank Website, 2023)
- ³ Ginkgo Bioworks is a company dedicated to creating new synthetic organisms that can be used in industrial settings such as pharmaceutical and fine chemistry industries. The company is founded by Tom Knight, famous for being one of the fathers of the internet and of modern computing. The US Department of Defense and the military maintains a close relationship with the company not only with FELIX, but also with other projects (TAYLOR, 2016; LONGWELL, 2018). Some companies’ directors and main advisors such as Shyam Sankar, Thomas Bostick, Renee Wegrzyn, and Adam Harmon have come from the military or from military contractors (BIOSPACE, 2021).
- ⁴ Can be seen at the ODNI website: <<https://www.dni.gov/index.php/what-we-do/ic-budget>> Accessed on 8 January 2023.
- ⁵ The full list of completed and underway projects can be found at the IARPA’s website at <https://www.iarpa.gov/research-programs?office_name=collection> and <https://www.iarpa.gov/research-programs?office_name=analysis> Accessed on 8 January 2023.
- ⁶ Can be seen at ODNI website: <<https://www.dni.gov/index.php/what-we-do/members-of-the-ic>> Accessed on 8 January 2023.
- ⁷ The Central Intelligence Agency and the Office of the Director of National Intelligence.
- ⁸ The Defense Intelligence Agency (DIA), the National Security Agency (NSA), the National Geospatial- Intelligence Agency (NGA), the National Reconnaissance Office (NRO), and intelligence elements of the five DoD services; the Army, Navy, Marine Corps, Air Force, and Space Force.
- ⁹ The Department of Energy’s Office of Intelligence and Counter-Intelligence; the Department of Homeland Security’s Office of Intelligence and Analysis and U.S. Coast Guard Intelligence; the Department of Justice’s Federal Bureau of Investigation and the Drug Enforcement Agency’s Office of National Security Intelligence; the Department of State’s Bureau of Intelligence and Research; and the Department of the Treasury’s Office of Intelligence and Analysis
- ¹⁰ (Snowden, 2019, p. 80)
- ¹¹ According to Dana Priest, by 2008, 28% of all intelligence community professionals were private contractors. (Priest, 2011, p.320)
- ¹² (Finnegan & Danysh, 2015)
- ¹³ The US budget to defense spending is around US\$400 billion annually (Bloomberg Government, 2003), while Brazil’s defense budget is around US\$20 billion, with over 80% of this amount reserved to pay for personnel salaries (Portal da Transparência, 2023).
- ¹⁴ State owned bank dedicated to financing Brazilian industrial production.

- ¹⁵ State owned company dedicated to oil and gas exploration as well as petrochemical refining and fine chemistry.
- ¹⁶ State owned retail bank.
- ¹⁷ State owned agricultural research company.
- ¹⁸ State owned aerospace company.
- ¹⁹ Political analysts regard the Ministry of Science and Technology (MCTI) weak because of the comparative amount of budget reserved annually to it: while ministries considered important - such as education or healthcare - have a budget of US\$20 billion or more, the MCTI has a budget of around US\$2 billion, including salaries and recurrent fixed costs (Portal da Camara dos Deputados, 2023).
- ²⁰ You can see more about the Brazilian army effort in biology and biotechnology at <<http://www.ibex.eb.mil.br>> Accessed on: 28 February 2023
- ²¹ While EMBRAPA has a total annual budget of around US\$700 million (EMBRAPA, 2023), the National Development Bank (BNDES) has an annual budget of around US\$40 billion (BNDES, 2022).
- ²² You can see a partial list of projects at <<https://www.spo.cnpqia.embrapa.br/temas-publicados>> Accessed on 1 March 2023.
- ²³ What are now called “dual use” technologies (Ruttan, 2006, p. 184)

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Combating the ‘Silent Crisis’ of the Donation Gap with ‘Polyphonic Relatedness’

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Abstract: The UK has been a global leader in the development and regulation of biobanks and bio-databases that facilitate clinical and laboratory access to tissue, blood samples, DNA and data. Yet the persistent barrier to mobilise non-White communities into actively contributing to and, subsequently benefiting from structural and scientific advantages that the UK can offer constitutes a ‘Silent Crisis’. This paper builds on ongoing research on stem cell donations carried out by the authors in the UK. We underline the centrality of the concept of ‘relatedness’ in donor recruitment, and the tricky role it has played, both as a uniting and an alienating force within and between different ethnic communities. We argue that the building of a thick societal relatedness or what we term as ‘polyphonic relatedness’ offers a constructive guidance to overcome the racial disparity in biomaterial donations.

Keywords: DNA, Data, access, bio-database

Introduction

‘Rakesh [Shah], died from a blood disorder at the age of just 35. Due to Rakesh’s Indian heritage, he struggled to find a donor with the 10 matching genes that would have helped ensure that his blood would accept the donor’s cells.’

— Mohammad Yasin. House of Commons, 2018

Rakesh Shah’s tragedy opened the UK parliament debate on the chronic deficiency of blood, stem cell and organ donation from Black, Asian and minority ethnic (BAME) communities on 27 June 2018. The UK has been a global leader in the development and regulation of biobanks and bio-databases that facilitate clinical and laboratory access to tissue, blood samples, DNA and data. Yet there has always seemed to be a persistent barrier to mobilise non-White communities into actively contributing to and, subsequently benefiting from structural and scientific advantages that the UK can offer. This is due to a simple medical fact that donor-recipient capability is determined by their biological relatedness, or more precisely

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put, by their human leukocyte antigen (HLA) similarities. One is more likely to find an HLA match among people of a similar ethnic background or ancestry. The racial disparity of donors and its immense health impact was characterised as a ‘Silent Crisis’ in a comprehensive review carried out by the Sheffield Street Company, commissioned by Member of Parliament Eleanor Smith (2018).

In the past few years, a number of scientific institutions and civic organisations, including high-profile individuals in the UK have been actively tackling this issue through education, targeted-campaign, and grassroots engagements. An economic calculation of using domestic stem cells which are cheaper than relying on an international market is an underlying policy rationale that encourages government-funded public bodies and health charities to join forces to improve service provision (Williams, 2015). However, a donor gap remains. According to the latest statistics released in May 2022, while the UK has reached a milestone of having more than two million people registered to become potential blood stem cell donors, the percentage of BAME donors remained at 13% (DKMS, 2022). Thus, little has changed with the dire disparity that patients from BAME backgrounds have a 20% chance of finding the best possible blood stem cell match from an unrelated donor, compared to 69% for northern European backgrounds (House of Commons, 2018; DKMS, 2022). Black donors make up only 1.2% of the British Bone Marrow Registry (Smith, 2018).

The persistence of the ‘Silent Crisis’ highlights an important yet often ignored pre-requisite for biomedical development to achieve the ‘common good’. That is, equitable public health outcomes hinge not only on robust infrastructures of bioeconomy, policy framework and competitive innovation workforce but also on the quality of participation from diverse communities. To put it in another way, how people relate themselves to the importance and the implications of a medical practice (such as curating a stem cell registry) is a critical part of fully realising the promises of social good of biomedicine.

This paper builds on ongoing research on stem cell donations carried out by the authors in the UK, in which we explore more effective ways to address the ‘Silent Crisis’. More specifically, we underline the centrality of the concept of ‘relatedness’ in donor recruitment, and the tricky role it has played, both as a uniting and an alienating force within and between different ethnic communities. The observed ‘silence’ from ethnic minority donors reflects an absence of a sense of relatedness to the biomedical agenda. We argue that the building of a thick societal relatedness or what we term as ‘polyphonic relatedness’ offers a constructive guidance to overcome the racial disparity in biomaterial donations.

In what follows, we will first unpack the role of ‘biological relatedness’ in stem cell research. We draw attention to the fine line between recognising genetic differences and not essentialising group identity or widening racial divides. We then provide an overview on how ‘relatedness’ is featured in existing initiatives in the UK and identity where there may be missed opportunities. Finally, we explain what we mean by ‘polyphonic relatedness’ and what it means for future research agenda.

The Role of Biological Relatedness in Stem Cell Research

Researching human genetic variation for biomedical research purposes is key to identifying risk factors and differentiated treatments (Risch et al, 2002). Biological relatedness is pertinent to stem cell research (Williams, 2021), especially research on translational medicine applications such as the focus of our ongoing work, the transplantation of donated haematopoietic stem cells. The success of haematopoietic stem cell transplantation depends on the type and degree of biological relatedness between donor and recipient; this ‘matching’ requirement between the donor and recipient is the same as that the principle applies to solid organ transplantation. In general terms, the higher the degree of this type of ‘biological relatedness’ between donor and recipient, the more likely it is the transplant will be successful. It is for this reason that siblings are usually the first port of call when a stem cell donor is needed. Where siblings are unavailable or not suitably matched, other relatives are explored as potential donors. Finally, if there are no suitable donors within the family, then national and international registries of stem cell donors are searched to find a matched unrelated donor (MUD).

A MUD is most likely to be found within the recipient’s same ethnic group because people from the same ethnic group tend to display a greater degree of biological relatedness to each other than to individuals from outside. There are several different scientific techniques for measuring how well donor and recipient are matched, with modern genomics techniques being the newest gold standard.

In 2001 the Human Genome Project elucidated the sequence of the human genome; this was a first draft, a reference for use in comparison studies (Lander et al, 2001). Indeed, part of the ‘grand vision’ of The Human Genome Project was to improve our understanding of genetic factors influencing human health on a global scale. But despite the Human Genome Project being an international collaboration involving 20 research centres in six countries including China, France, Germany, the United Kingdom, Japan, and the United States, the reference genome produced was Euro-centric. This is not said to diminish the colossal achievements of the project but simply to introduce the historic under-representation of non-European ethnic groups in genomics datasets. The authors were more

than aware that obtaining a draft sequence of the human genome was the beginning of a new era of ‘genomic medicine’, including an explosion of work around the influence of genetic variation on human health and disease (Collins, 2003). The concluding thoughts of the original publication of The Human Genome Project state: ‘Finally, it has not escaped our notice that the more we learn about the human genome, the more there is to explore’ (International Human Genome Sequencing Consortium, 2001).

Since the Human Genome Project, there have been successions of efforts to genomic databases more representative of the diversity of global communities. The African Genome Variation Project (Gurdasani et al, 2015) and the GenomeAsia 100K Project (GenomeAsia100K Consortium, 2019) are two most well-known programmes that hope to address the chronic under-representation of non-European ethnic groups in genetic datasets. This important work recognises the genetic diversity of human populations and incorporates it into the body of scientific knowledge such that this fundamental, gene-level understanding of human health and disease is applicable to a larger proportion of the global population.

In short, the science of genomics, through measuring biological relatedness, can empirically describe the biological elements of ethnicity. But it must be reminded that the point of genetic *categorisation* for biomedical research purposes is to better *recognise* and *incorporate* diversity, so as to better *attend* to individual particularities. Good science necessarily takes into account multiple factors (biological and non-biological) in its understanding of a disease or of treatment, rather than seeing people as neatly demarcated groups. To put it in another way, the ethnic lens used in biomedical research and in stem cell sampling is to help map out human diversity rather than to reduce it to rigid conceptual boxes.

In fact, there has been a growing recognition on how international migration has blurred the lines of conventional categorisations of race. Similar to many other countries, ‘multiracial populations’ are the fastest growing ethnic group in the UK (Solomon, 2017; Henderson, 2022; Atkin et al, 2022). The number of Britons who self-identify as mixed-race almost doubled between the census of 2001 and 2011. Mixed-race people currently make up 16% of all non-whites in the UK, while the figure is 11% in the US (Nandi and Platt, 2020, 23). Mixed-race individuals often have much more difficulties in finding a donor (see ASCO, 2021 and the Mixed Match Project).

In short, our biological differences are both real and messy. For stem cell registries to generate equitable health benefits for all citizens, it requires diversified profiles of donors. This point is important. As the next sections demonstrate a common approach to drive up stem cell donation capitalises on biological relatedness and relies on an ‘ethico-racial imperative’ rhetoric

(Williams, 2021). While such an approach has shown some effect in the short run, we argue that the ‘ethics-racial imperative’ framing alone is misleading and could be counter-productive in the long run. What lies at the heart of the Silence Crisis is not a competition between different races and ethnicities but is part of a larger disjointedness of contemporary bioscience with minority groups. Its solution also calls for attentiveness to another type of relatedness, that is, the social relatedness of bioscience to citizens from diverse ethnic backgrounds.

Existing Approaches to the Silent Crisis and Their Limitations

It is safe to say that the aforementioned 2018 review of donor disparity commissioned by the British MP Eleanor Smith not only renders better visibility to the donation disparity, but it also encompasses a general framework for how this disparity is analysed and addressed. The review identified three factors as the main reasons for low participation from BAME communities (Smith, 2018, 8). They are: 1) lack of awareness or of access to information on donations, 2) religious permissibility and 3) lack of trust in medical institutions and a fear of medical exploitation along class and ethnic lines. Correspondingly, the 2018 review made a comprehensive list of suggestions, such as creating a culture of donation through public campaigns, integrating information about donation into school curriculums, normalising collaboration between medical institutions and local faith leaders, targeting engagement with grassroots BAME communities, and increasing ethnic diversity in NHS staff (Smith 2018, 12-7).

Two general rationales can be seen across different initiatives that have been carried out in the UK. One is a focus on reaching out to young people through education and targeted campaigns. Following the parliament debate, the UK Department for Education introduced guidelines for secondary schools to teach their pupils ‘about the science relating to blood, organ and stem cell donation’ (DfE 2018, 2019, p. 37). Anthony Nolan (<https://www.anthonynolan.org/>), a blood cancer charity, hosts a registry for donors until the age of 61. But its recruitment is focused on healthy individuals aged between 16 and 30. The focus on younger generations has at least two advantages. One is that it helps to cultivate cultural change through upcoming generations in different communities. The other is that donations from young healthy individuals have higher clinical success rates for patients.

The second general rationale is working from inside ethnic minority communities. The UK’s National Health Service (NHS) hosts the Community Grants Programme (formerly the Community Investment Scheme) dedicated to ‘build[ing] support for donation amongst Black, Asian, mixed heritage and minority ethnic communities’. In their latest call

launched in December 2022, a total of £700,000 was committed to support community-based projects across England and Wales to raise awareness of donations. Individuals of influence (e.g. community leaders, elderly people, or celebrities of colour) are often considered key in mobilising stem cell donations within the ethnic community they resemble. It is also not uncommon for civic initiatives to be developed through racial lines. For example, the Iman Hussain Blood Donation Campaign in Manchester is focused on Muslim communities, while the African Caribbean Leukaemia Trust focuses on black communities. Ethnic narrative is embedded in many media campaigns as well, such as Dev Patel, the *Slumdog Millionaire* actor's public appeal for stem cell donors to save the life of a young British South Asian boy (<https://fb.watch/i96IIuX0aS/>).

However, this is also where a paradox seems to arise. That is, while ethnic specific initiatives may help incentivise donations from an immediate community and establish islands of specialised registry, it also amplifies the *social* construct of racial difference and thus aggravates a *social racialisation* of biomedicine, which was, arguably, a major cause of ethnic minority groups' non-engagement in the first place.

In her series of discussions on UK stem cell donation strategies, Ros Williams has pointed out how the idea of 'relatedness' was exploited in the context of race, in which 'racialised suffering' is used to invoke 'racialised obligation' of donation (Williams, 2021, 482, 486). The pursuit of diversifying samples for stem cell banks has effectively resulted in British scientific communities aligning one's HLA type with their ethnic identification, a practice that Williams considered as 'alarming' for it reinforces the racial divide (Williams, 2015). Existing norms of community-engagement and their varied success also raises 'an uncomfortable and not easily answerable question': 'What does it tell us that so much of the ongoing and difficult work to ameliorate health inequalities is actively placed in the hands of racialised communities themselves, rather than framed as a collective onus borne by us all, regardless of how we identify or are read, to address the historical striations of inequity that our health systems so urgently need addressed?' (Williams, 2021, 488). In addition, an 'ethics-racial imperative' rhetoric has its limit. In particular, why minority individuals may 'elect not to engage with biomedical projects' (Williams, 2021, p. 487) remains under-explored (see also Amendola, et al 2018).

We hope to address questions provoked by Williams' research. While we consider both reaching out to younger generations and purposeful grassroots engagement as critical, we also argue that reflecting on the purpose and on what it means to engage with ethnic minority communities is vitally important.

Studies have suggested that the concern over race and ethnicity as a barrier to biomedical participation itself has been treated uncritically

(Hartigan, 2008; Landry, 2021; Young et al, 2022). Race and ethnicity could be confounding factors that are wrongly used to ‘blackbox’ a number of issues that distance non-white communities from actively participating in donations. The point here is not to underplay the value of targeted engagement with minority communities but to highlight that the substance of the engagement (e.g. how we engage and what the goals should be) cannot be taken for granted and requires further empirical investigation.

For example, uncritical reiteration of the correlation between mistrust in medical institutions and a particular race could create a false perception of that ethnic community as non-trusting or could underplay more systematic problems. A large-scale study on decisions about unrelated hematopoietic stem cell donation among White, Asian/Pacific Islander, Hispanic and African-American populations showed that ‘doubts and worries’ was ‘the most consistent factor associated with opting out of the registry across all race/ethnic groups’ (Switzer et al, 2013, 1469). Another recent study on Hispanic, non-Hispanic White, Asian, and biracial families’ rationales in participating clinical genomics research found that, contrary to conventional impression, Hispanic families have shown more trust in providers than parents from other ethnic background (Young et al 2022, 6). This is of course not to negate a general scepticism and distrust that historically exploited and excluded ethnic groups have towards (Western-dominant) modern medicine, but to underline the often-ignored fact that how one relates to the health system is not dictated by one’s genetic heritage, but is situational, empirical and always evolving (Gaskell et al, 2013, Passmore et al, 2019).

A reflexive and non-essentialist approach to minority communities is especially pertinent for any future-oriented engagement work with potential donors from varied sociodemographic backgrounds to be effective. As the future population is increasingly mixed-race, conventional boundaries of identity politics are increasingly difficult to hold (Solomon, 2017; Nandi and Platt, 2020). To improve diversity in biomedical research, rhetoric and strategies rooted in reinforcing rigid regimes of *biological relatedness* are short-sighted and could be counter-productive in the long run. The chronic shortage of stem cell donors from diverse sociodemographic backgrounds underlines a broken societal connectedness between the field of stem cells and non-White communities. We need to address the Silent Crisis by building ‘*polyphonic relatedness*’ that creates a deep and sustained connection between ethnic minorities and (individual and collective) future health.

Polyphonic Relatedness and An Agenda for Future Research

A polyphony refers to a rich texture of music in which two or more independent melodies are simultaneously present. By building ‘polyphonic relatedness’, we mean the creation and curation of biological and socio-

political connectedness between individual citizens (especially those from ethnic minority backgrounds) and biomedicine through the interblending of different voices. We argue for methodological innovations in how we engage with ethnic minority communities and a re-orientation of what engagements such as donor campaigns should be aiming to achieve.

When discussing widening participation and engaging with marginalised or disadvantaged groups, we often talk about ‘voice’. In widening stem cell donations, it is essential to listen to communities’ needs and cultural and religious particularities. But what if a community does not have a *coherent* voice? What if there are different voices within the same community? To further complicate the scene, ‘community’ is also a social construct. Membership to a community can be assigned, bestowed, or self-identified. One’s relationships with different communities are always overlapping and forever evolving. Few would dispute that good engagement is to enable new communities and new relatedness to emerge. But how do we avoid the reductionist temptation of rectifying racial divides, so that we can still purposefully identify social groups to diversify donors but not lose sight of in-group diversity and the necessary fluidity of its composition? When we reach out and try to build connections with ethnic minority communities, how we can better encourage and make sense of different voices?

Answers to these questions may be contextual. Racial disparity in stem cell donations is a global problem with community level solutions (APPG, 2021). Purposeful engagement necessarily needs to start with the engagement of a particular group of individuals (for example, our ongoing research focuses on black communities). But it should bridge rather than reinforce racial divides. Building polyphonic relatedness offers an effective and sustainable framework for finding solutions to the Silent Crisis for the following reasons:

- 1) At a basic level, building polyphonic relatedness is enhanced listening and enhanced articulation. By enhanced articulation, we mean going beyond a simple framing of ‘racialised suffering’, to integrate different accounts of the multi-layered interdependence and interrelatedness that is embodied in the registration, participation and utilisation of stem cell registries. It also requires giving a clearer account of the short term and long term impacts of building diverse stem cell registries. Only through providing a more comprehensive account can biomedical institutions become more ‘account-able’ to ethnic minority groups. It also helps to shift the narrative from calling upon ethnic minorities to solve a crisis to bolstering their readiness to join collective scientific endeavours. Culturally sensitive articulation requires enhanced listening, which does

not treat ‘what we hear’ as static and dogmatic. Polyphonic listening is to appreciate in-group diversity, such as generational differences, socioeconomic differences and to recognise cross-group memberships.

- 2) Building polyphonic relatedness is to co-narrate and co-discover the importance of stem cell donation. Relatedness should be two-way. Engagement and collaborations with local communities should focus both on educating how stem cell registries *relate to them*, and on learning how they *relate themselves to* (or would like to relate themselves to) biomedical research. This is a necessary step to allow new relatedness to be discovered and to be developed. However, currently, most research on mobilisation of minority donors has mainly focused on how to adapt recruitment messages to fit in with particular cultural norms (i.e. how to relate recruitment goals to local communities), rather than evoking a sense of partnership and vision of biomedical development from minority communities (i.e. how they (wish to) relate themselves to biomedical development).
- 3) Building polyphonic relatedness enables an active form of biological citizenship. Bio-citizenship is a concept first coined by Andriana Petryna (2002) to describe a somewhat passive right, that is the state’s obligation towards welfare claims made by a biologically damaged population. Nikolas Rose and Carlos Novas (2005) later extended this concept by highlighting the unavoidable entanglement of one’s identity and biotechnology, and how this gave rise to new forms of subjugation as well as public participation in socio-political domain. Biomaterial donation could rely on the rhetoric of passive biological citizenship (e.g. it’s one’s duty to save the life of an ethnic peer), or it could rely on an active form of biological citizenship (e.g. it’s one’s choice or preference). These two forms of bio-citizenship are not mutually exclusive. But arguably, a fairer and more sustainable bioeconomy would benefit from more practice of active biological citizenship. This requires policy and structural support that can help reduce socio-economic, geographic barriers to participation (APPG, 2021). But it also requires a cultural change. That is, in addition to enhancing scientific literacy itself, more individuals could relate themselves to biomedical advancement, and actively reflect on and contribute to its development. This is where community level engagement makes a difference.

The framing of ‘relatedness’ lies at the heart of the chronic problem of under-recruitment of ethnic minority donors. We’ve demonstrated that

a conventional approach of mobilising minority donors often over-relies on biological relatedness, which paradoxically aggravates rather than bridges racial divides. What has been overlooked is curating ‘polyphonic relatedness’ between disadvantaged groups and biomedical institutions, through enhanced articulation and listening, evoking partnership, and enabling active biological citizenship. In short, polyphonic relatedness enables a constructive and liberal realm for conversation and collaboration where, as poet W. H. Auden elegantly put:

Our several voices
Interblending,
Playfully contending,
Not interfering
But co-inhering.

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Short Case Studies

Centella asiatica Complex Health Tea: Opportunities and Challenges in the Development of a Commercial Product Based on Indigenous Knowledge

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Abstract: *Centella asiatica* (commonly known as gotu kola, the Chinese name is *Jixuecao*) has a long history of application and is widely used in many countries. Ethnobotanical fieldwork with Buyi villagers in Guizhou Province, China revealed that *Centella asiatica* is one of the most frequently consumed herbal teas. This paper reports on the nutritional value of *Centella asiatica* and some preparation methods for a new complex health care tea that we developed with it. The main objective of this short case study is to reflect on the social and ethical implications of developing a commercial tea product based on traditional ethnobotanical knowledge.

Keywords: *Centella asiatica*; Health tea; nutritional value, Ethnobotany, Indigenous Knowledge

Introduction

Wild plant resources play an indispensable role in maintaining the livelihood security of people in resource-deficient areas and in balancing the nutritional value of their diets (Cunningham 2001). Ethnobotany is an interdisciplinary field of study that explores all aspects of the relationships between people and plants, especially those that come from the wild. Throughout much of its history, the field has been closely aligned with economic botany and has had an emphasis on the values and uses of plant resources (i.e., traditional botanical aspects of the bioeconomy). Ethnobotanists have been instrumental in both the development of commercial products based on indigenous botanical knowledge and the establishment of ethical guidelines for engaging in such commercial ventures. Herbal teas are consumed all over the world and their commercial value and development have been hotly debated within and beyond ethnobotany. Van Wyk and Gorelik (2017) argue that it's important to have accurate historical records of plants that can be used as tea. They explain that such documentation increases the likelihood that plants are safe and pleasant to consume and also helps protect intellectual

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property rights. In this paper, we look at the contributions of indigenous knowledge and phytochemical analysis in the development of safe, pleasant and equitable herbal teas.

In China, there is a distinction between tea (i.e. *Camellia* spp.) and herbal tea. ‘Herbal tea’ usually refers to plants used to make infusions, which do not belong to the *Camellia* genus of the Theaceae family. While the use of *Camellia* spp. infusions as hot, stimulating beverages originated in China, the country has a long history of using many other plants as tea beverages in some areas and ethnic groups. Guizhou is where many ethnic minorities have lived for generations. Local people have produced a variety of lifestyles and life practices. The Buyi people in Guizhou have accumulated a rich culture of herbal tea resource utilization and *Centella asiatica* (Buyi name ‘bian nuo’) has been used for centuries. *Centella asiatica* has also been known as a commonly used traditional Chinese medicine since ancient times and first appeared in “Shen Nong’s Herbal Classic.” It tastes bitter, pungent, and cold, and according to traditional Chinese medical theories, the bitterness returns to the liver, spleen, and kidney meridians. It has the effects of clearing away heat and dampness and detoxifying and reducing swelling.

After reporting on the nutritional value of *Centella asiatica* and providing some preparation methods for a new complex health tea made of *Centella asiatica*, the main objective of this short paper is to briefly reflect on the social and ethical implications of developing a commercial tea product based on traditional ethnobotanical knowledge.

Ethnobotanical Research, Nutritional Analysis

Free lists (i.e. asking research participants to list all the herbal tea plants they know) and semi-structured interviews were conducted in local Buyi households in Qianxinan Prefecture in southwestern Guizhou in 2021. The aims were to find out what plants they use as a tea, what various teas are used for, how they are used, and when/where tea plants are collected. According to free list data, *Centella asiatica* was one of the most frequently mentioned plants by local Buyi informants (Figure 1). Chemical components and their relative contents in the leaves of *C. asiatica* were tested by Weilaikeji company using LC-MS technology. A preliminary sensory evaluation of the completed *Centella asiatica* complex health tea was carried out to find out the taste, aroma and soup color of the complex tea following the National Standard for Tea Sensory Evaluation Methods (GBT 23776-2018). This is a common evaluation method for tea products in China that uses the sensory organs to determine the taste, aroma and soup colour of the tea.

The nutritional assessment showed that leaves of *Centella asiatica* have certain health functions, and the flavonoids and polysaccharides

contained in *Centella asiatica* have antioxidant properties (which are important in the elimination of oxygen free radicals) (see Table 1). There is a high content of water-soluble substances (35.18%), chlorogenic acid (613.18 ug/g), phenolic compounds (22.19 mg/g) and total flavones (17.56 mg/g) (Table 1) in the leaves. The leaves also contain various nutrients, such as protein, carbohydrates, alkaloids, vitamins and minerals etc. and the composition of their compounds is influenced by different biotic and abiotic factors (Ajayi et al. 2020; Brinkhaus et al. 2000; Ren et al. 2021; Shao et al.; 2004; Siddiqui et al. 2007; Zheng et al. 2022). A functional beverage made from *Centella asiatica* can be recommended for people who are subject to excessive stress and anxiety, struggling with alcohol abuse, or interested in enhancing the intellectual activities of workers (Khasanov et al. 2021).

At present, there is no research or report showing that *Centella asiatica* will produce toxicity in common doses. Side effects are rare, but skin allergies and burning sensation (for external use), headache, gastrointestinal discomfort, nausea, and dizziness cannot be ruled out. In some special cases symptoms such as extreme drowsiness may also occur at high doses (Gohil et al., 2010; Khasanov et al., 2021). Also, there is little evidence that *Centella asiatica* can be used safely during breastfeeding, so it is advised that its use by breastfeeding mothers is avoided.

Table 1 Nutritional value of *Centella asiatica* leaves

Nutritional index	value	Nutritional index	value	Nutritional index	value
DPPH (µg Trolox/g)	216.25	VC (µg/g)	8.70	Crude fat (%)	1.81
ABTS (µg Trolox/g)	942	Chlorogenic acid (µg/g)	613.18	Crude fiber (%)	16.15
Reducing sugar (mg/g)	2.80	Caffeic acid (µg/g)	18.87	Water-soluble substances (%)	35.81
Soluble sugar (mg/g)	44.98	P-Hydroxycinnamic acid (µg/g)	10.42	Total acid (g/kg)	1.36
Flavonoid (mg/g)	3.86	Ferulic acid (µg/g)	11.46	Fe (mg/kg)	187.88
Total alkaloid (µg/g)	1988.68	Rutin (µg/g)	1157.61	Mn (mg/kg)	579.04
FRAP (µmol FeSO4/g)	8.31	Quercetin (µg/g)	56.62	Na (mg/kg)	87.11
Total polysaccharide (mg/g)	62.73	GA (µg/g)	3.75	K (g/kg)	17.55
Phenolic compound (mg/g)	22.19	EC (µg/g)	61.06	Ca (g/kg)	11.28
Total flavone (mg/g)	1756	Ash (%)	9.99	Mg (g/kg)	4.91
Total saponin (ug/g)	29734.96	Dry matter (%)	13.97	-	-

Source: Author on Compilation

Beverages using dry plant extracts of *Centella asiatica* on its own or blended with other plants also have been shown to have functional and biologically active properties (Chandrika *et al.*, 2015; Khasanov *et al.*, 2021; Rohini and Smitha, 2022). However, *Centella asiatica* tastes quite bitter as the raw material of a functional health tea. Therefore, we developed a process of adding flower buds of jasmine in the preparation of ‘*Centella asiatica* complex health tea.’ Jasmine was selected due to its mellow fragrance and low cost. The preparation steps are as follows-Firstly, fresh *Centella asiatica* leaves were placed in a steamer for 3-5 mins (i.e. more than 3 mins of steaming to remove the grass gas) and were spread out in a cool and ventilated place. Next, 2-4 jasmine buds were tied with *Centella asiatica* leaves using food-grade cotton thread to create *Centella asiatica* tea bags. The tea bags were then dried at a temperature of 35-45 °C for 12-15 hours. Tea bags were cooled on a perforated screen for 0.3-1 hour in a cool, ventilated place. Finally, the bags were freeze-dried by vacuum until the moisture content was between 7% and 10%. Based on these methods different conditions were applied to the cooking process of the raw materials and the drying process of the complex health tea (Figure 2 and 3). Sensory evaluation (see Table 2) was then used to identify the optimal recipe.

Combining Indigenous Knowledge and Nutritional Analysis

Centella asiatica Complex Health Tea was inspired by ethnobotanical fieldwork in Guizhou, China with members of a Buyi community. The Buyi are one of the 55 minority socio-linguistic groups recognised in China. They speak their own indigenous language (Buyi) and have developed an ethnomedical system that is distinct from Traditional Chinese Medicine. This includes a significant amount of traditional ecological knowledge about the

Table 2 Sensory review of *Centella asiatica* complex health tea made in different methods

	Processing	Color	Aroma	Taste
Treatment 1	Steam 0min, 40°C baking 13h	Yellowish green	Green grass	Green taste
Treatment 2	Steam 3min, 45°C baking 13h	Light yellowish green	Thin aroma	Light
Treatment 3	Steam 4min, 45°C baking 14h	Lush green	Pure; Jasmine	Mellow; Flower
Treatment 4	Steam 5min, 40°C baking 15h	Tender green	Pure and normal; More lovely; Jasmine	Mellow and thick; Flower

Source: Author on Compilation

medicinal plants in their environments (Xiong and Long, 2020). Results of the ethnobotanical fieldwork with the Buyi indicated that *Centella asiatica* is one of the most widely consumed herbal teas in the study community. The increasing number of medicinal compounds that have been identified from this plant, as well as our own nutritional analysis, suggest that it has the potential for development as a functional health tea. With additional research and development, we hope to attract the attention of an herbal tea manufacturing company that can develop *Centella asiatica* Complex Health Tea into a commercial product that will benefit Buyi communities in Guizhou.

However, the fraught history of the development of pharmaceutical drugs based on indigenous ethnobotanical knowledge (see for example Hayden, 2003) suggests that combining indigenous knowledge and nutritional analysis to make a functional health beverage is delicate and complex. Ethical guidelines for ethnobotanical research emphasise that researchers, commercial product developers and the indigenous communities that they work with should agree on equitable benefit sharing arrangements as early as possible. Yet doing so can be difficult to put into practice. The Buyi are one of the larger ethnic minority groups in China with a population of almost 3 million (Xiong and Long, 2020). It is likely that *Centella asiatica* is well-known in many if not most Buyi communities. If the Buyi-inspired *Centella asiatica* Complex Health Tea were to be developed commercially, before any benefit sharing agreement could be put into place, we would need to determine who the beneficiaries would be.

Typically, such agreements are entered into with indigenous organizations, rather than with individuals or even individual communities (see Wynberg, 2004). Given how widespread ethnobotanical knowledge of *Centella asiatica* is, is it best to find a local group that represents our study community, or a larger Buyi organization? If a product was developed based on knowledge from Guizhou, how might Buyi groups in other provinces benefit from the commercial development of this knowledge? Furthermore, *Centella asiatica* is used by other ethnic groups in China (including in Guizhou), as well as in many other Asian countries. How best to represent the interests of all holders of traditional ethnobotanical knowledge of this popular plant? Is this even possible?

A final factor to consider is the potential impact of commercial development on the plant itself. There are many examples of wild plant resources that have been threatened due to the unexpected popularity of their commercial development. The native range of *Centella asiatica* extends throughout the Eastern Hemisphere. The species is abundant and widely distributed in southern China. In some places, it is even regarded as a weed (Prakash et al., 2012; She and Watson, 2005). This suggests (but does not guarantee) that *Centella asiatica* has potential for equitable and sustainable development.

In addition to considering the rights and needs of all human stakeholders, bioeconomic development for the common good must also include our botanical partners. This of course raises further questions. What are the most effective ways of monitoring plant population health and species abundance? What are the most sustainable ways of harvesting *Centella asiatica* and how cost-effective are they? Who is responsible for keeping plant populations healthy and ensuring that resources are harvested and managed sustainably?

Conclusion

Centella asiatica has a long history of application and is widely used in many countries. We found that it was one of the most frequently named species in free lists of herbal teas used by Buyi villagers in Guizhou, China. In this short report, we presented the results of a nutritional analysis of *Centella asiatica*, and the development of a complex health tea product made with jasmine. Jasmine adds aroma and visual impact to *Centella asiatica* complex health tea. This not only addresses the flavour deficiencies of *Centella asiatica*'s bitter and cold nature, but also enhances the medicinal value of the active ingredients of *Centella asiatica*, making it easier to be accepted by the public. The preparation method of the *Centella asiatica* complex health tea retains and integrates the characteristics (i.e. the aroma and taste) of raw materials, and the whole preparation process is relatively simple and easy to operate. This work suggests that *Centella asiatica* is a good candidate for further development as a functional health beverage.

However, we also reflected on the issues that will need to be addressed in order to develop this bioeconomic product so that it benefits the common good. The inspiration for developing *Centella asiatica* Complex Health Tea was indigenous Buyi knowledge of herbal tea plants, and our research community has a stake in any commercial product developed from their knowledge. But the people who answered our interview questions are not the only holders of traditional knowledge of *Centella asiatica*. Such knowledge is shared collectively by many indigenous communities (as well as the Han majority population) in China and beyond. There are many examples of benefit sharing agreements between pharmaceutical developers and the communities that share their traditional ethnobotanical knowledge with them. But they suggest that the creation of such agreements so that they are truly equitable is far from straight forward. Answering the questions raised in this short communication requires multi-disciplinary research (by anthropologists and other social scientists, as well as botanists and ecologists). Thus, ethnobotany has an important role to play in the commercial development of plant products that promote health, based on indigenous and traditional knowledge.

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Figure 1 *Centella asiatica*



Figure 2 *Centella asiatica* compound health tea ingredients

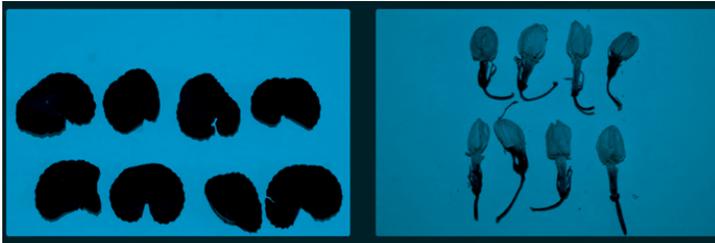
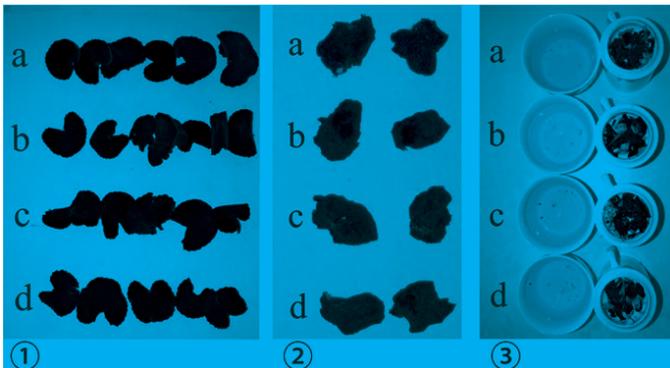


Figure 3 Different preparation methods and sensory review of *Centella asiatica*



Health Tea

Notes. 1) *Centella asiatica* with different steaming times; 2) Hand preparation of *Centella asiatica* composite health class tea products; 3) *Centella asiatica* composite health tea broth and leaf base; In the fig. 3, a represents Treatment 1, b represents Treatment 2, c represents Treatment 3, and c represents Treatment 4 (table2).



Application of CRISPR–Cas in Ageing and Health Equity

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Wei Yang**

Abstract: The recent advances in CRISPR-Cas technology have shown great potential in tackling age-related diseases and pathologies. However, older people from disadvantaged groups are less likely to have access to this technology compared to those from the more advantaged background. In particular, research shows that older people from certain minority groups may have concerns about participating in CRISPR-Cas-related research due to mistrust of this technology. This may lead to the underrepresentation of certain minority groups in the research, hence affecting the effectiveness of the CRISPR-Cas-related treatment. CRISPR-Cas may also have limited applications for the poor and those who live in less developed regions where this technology is either too expensive or not available. We urge governments to address the issue of equitable access to CRISPR-Cas technology by involving underrepresented groups in research, improving the ethical diversity in genomics databases, and reducing financial barriers to accessing the technology.

Keywords: CRISPR–Cas, Ageing, Health Equity, Accessibility.

Researchers have developed new gene therapies to help to slow down the ageing process or tackle age-related pathologies, such as neurodegenerative disorders, cancers, and other metabolic diseases. In particular, CRISPR–Cas (clustered regularly interspaced short palindromic repeats and CRISPR-associated genes), a potent gene-editing tool, has demonstrated the potential in correcting some of these ageing-related pathologies by ameliorating symptoms or curing diseases. Although advances in gene-based therapies and treatments provide opportunities for personalized medicine, disadvantaged older people may not benefit from these advances due to access barriers or affordability issues. The purpose of this paper is twofold: firstly, it seeks to provide a review of current applications of CRISPR–Cas in ageing; secondly, it discusses the potential issues in equitable access to this technology among older people.

One of the most common applications of CRISPR–Cas system is to treat age-related diseases. CRISPR–Cas works as a gene-editing tool in

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correcting gene-mediated age-related pathology, which can be used to delete target genes and correct gene mutations. Clinically it has been translated to medicines or therapies for Alzheimer's disease or other neurodegenerative diseases (Jo et al., 2015) and reducing gene-targeting inflammatory molecule production to treat metabolic or inflammatory diseases (Jing et al., 2015), and in some cases, treating cancer (Kim et al., 2017). Another application of the CRISPR-Cas9 system is to offer a new novel approach to understanding anti-ageing research on ageing-related genes and pathologies. For instance, researchers found that the CRISPR-Cas9 system contributes to identifying genes that could affect cellular senescence where cells cease multiplying but continue to trigger inflammation and induce cell death (Wang et al., 2021). Liu et al. (2019) used a CRISPR-Cas9-based screen to find several gene deficiencies connecting to cellular senescence bypass, and these associated genes could be used to initiate or facilitate senescence. CRISPR-Cas9 also works as a tool by allowing the manipulation of gene function and regulation in traditional models of ageing and informing research on ageing processes such as cellular senescence and telomeric attrition - the loss of protective caps of chromosomes (Haston, et al., 2020). The potential application of CRISPR-Cas in anti-ageing practice involves interventions in DNA repair pathways and the ageing process. Li, et al. (2020) found that CRISPR is able to allow the correction of anomalous genetic functions, which may allow people to age without significant decreases in quality of life (Adli, 2018). Wang et al. (2021) found that genome-editing therapy using the CRISPR-Cas9 system offers a new approach to slow the progression of ageing. Hutchinson-Gilford progeria, a genetic disorder, provides an ideal ageing model for researchers to target molecular drivers of ageing (Salk Institute, 2019). Beyret et al. (2019) successfully developed a CRISPR/Cas9 genome-editing therapy to decelerate the process of ageing among progeria mice. These technological breakthroughs shed light on seeking new interventions to suppress ageing progress for human beings.

Although CRISPR-Cas9 can potentially benefit all communities, a number of barriers to equitable participation in and benefit from this technology exist. First, minority groups have barriers to equal participation in research. Racial and ethnic minorities and disabled people may have experienced unequal treatment in research and received inferior care (Benz, et al., 2011). This may be worse among older people due to potential functional decline and low motivation for participating in research. The disadvantaged groups may have concerns about the potential misuse of this technology in genetic enhancement to further increase health disparities and unjust resource allocation (Hildebrandt and Marron, 2018). The mistrust of research among older or minority populations may lead to an underrepresentation of certain minority groups in genomics databases.

An example of this lack of diversity of populations is the Genome-wide Association Studies Catalogue where the African respondents only represent 3% of the total sample (Popejoy and Fullerton, 2016).

Second, if the underrepresented population becomes an issue in genomic research, the lack of ethnically diverse groups in datasets may also impede scientists' capacities to understand the full genetic diversity spectrum, which may hamstring clinical care (Sirugo, et al., 2019). Considering the genetic differences, the gene therapy treatment, which is yielded from datasets lacking ethnic diversity, may be less effective, or even unsafe for certain populations (Popejoy and Fullerton, 2016). Likewise, it may also result in a higher risk of misunderstanding genetic variations and misdiagnosis for certain groups. This is exemplified by the mistakes in classifying benign hypertrophic cardiomyopathy variants as pathogenic among black Americans (Manrai et al., 2016). There are also significant racial differences in hypertrophic cardiomyopathy variants (Torii et al., 2017). Involving more ethical populations in these studies would prevent this misclassification and these misclassification reports highlight the need for sequencing populations across multiple ancestry backgrounds (Manrai et al., 2016).

Third, there could also be potential inequalities in terms of the affordability of this technology among older people. The costs for gene medicine or therapies can be hefty for ordinary people when the technology becomes commercially available because older people often have greater health and long-term care needs but are also poorer due to being over the working age (Abdi, et al., 2020). This issue may be even more pronounced among those older people from low- and middle-income countries or living in rural areas where such technologies may not be available or are less developed. (Etieyibo, 2012).

To sum up, in order to ensure equitable access to the application of CRISPR–Cas, it is imperative to involve underrepresented groups in the research, improve the ethical diversity in genomics databases, and to reduce financial barriers to accessing the technology locally and globally. We also urge governments to take actions to address equity issues by establishing a sound, ethical, and equitable governance system of this technology (World Health Organization, 2022).

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Wisdom of Inclusion for a Fairer Global Bioeconomy

Di Zhang*

Abstract: It is argued by some scholars that China can contribute to global bioethics in terms of new ideas and principles and construct its own bioethics theory. The Chinese idea of multi-faceted inclusivity, ‘Jian Rong Bing Bao’ is a potential one for this. It embodies inclusivity and humility and can facilitate open communication and engagement. In this brief article it is argued that ‘Jian Rong Bing Bao’ can be one such idea that can be taken forward. Based on equal respect and mutual dialogue the relevance of this idea can be developed without any claims of superiority. Further it can help in conceptualizing fairer bioeconomy globally.

Keywords: Bioeconomy, Fairness, Bioethics, Jian Rong Bing Bao, China

In 2015, the scale of China’s bio-industry exceeded 3.5 trillion, of which the bio-medical industry is developing particularly rapidly, and the bio-industry reach 10 trillion yuan in 2020 (Li & Wang, 2022). China’s rise in science, technology, and economics spark both geopolitical concerns and hope. Some concerns are that China may use “debt-trap diplomacy” to extract strategic concessions through the Belt and Road initiatives (Kuo & Kommenda, 2018). But some believe China can become “a beacon of reference for other countries” (Aires, 2022).

Some Western scholars suggest that China should construct its own bioethics theory, and that may benefit bio-governance both for China and the world. That is a good suggestion, and a few Chinese bioethicists are engaged in it. But I insist that we must be cautious with it. Overemphasizing Chinese or Western traditions, and labeling a theory as West, East or China may have a negative impact. Persisting with a China vs West dichotomy does not help reconcile differences but perpetuates the process of “Othering”. These labels can deepen the ideologization of theories and hinder dialogue between countries.

There is little dispute that the rise of the world’s second largest economy in biosciences significantly expands global possibilities for a better future. But as a bioethicist who has worked in ethical legal and social issues for nearly ten years, I believe to identify where China’s contribution to a fairer global bioeconomy lies, we first need to embrace the wisdom of inclusion.

I believe If any ‘Chinese’ wisdom can be used as a guide for coordinated global actions in the future, then the phrase ‘Jian Rong Bing Bao’(□□□□),

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a Chinese expression for multi-facet inclusivity, could be a key, not limiting to the subject of bioethics and bio-governance, but on other scientific issues as well. I want to highlight two points in this piece. First, Jian Rong Bing Bao is about ‘invite others’ and ‘self-reflection’. Second, it is enlightening for academic dialogue within China and between China and other countries, and it can promote global governance in science and technology.

Jian Rong Bing Bao

“Jian Rong Bing Bao” was coined by historian Sima Qian (Sima, 118 B.C.), to refer to individuals who have the humility to collect and embrace various strengths (such as thoughts, skills, knowledge and culture) and the capacity to assimilate different ways of thinking. In 1917, Cai Yuanpei, former president of Peking University, further put forward the idea of *Si Xiang Zi You, Jian Rong Bing Bao*(□□□□, □□□□) (Gao, 1984, p.271). Mr. Cai thought that the university should treat all kinds of academic ideas and thoughts equally, and encourage their free development even if they are opposed to each other, as long as they can justify themselves. Its purpose is to promote the expression and exchange of ideas and to advance the search for truth, rather than to make it imperative for all people to agree on one idea (Gao, 1984: p. 271).

I want to highlight that the wisdom of Jian Rong Bing Bao is not limited to simple advocacy of mutual respect and inclusivity. It prevents individuals from using the power to suppress the voices of others or using prejudice about the social identity of others to exclude them.

In particular, there are two important points embedded in the Chinese wisdom of inclusion. Firstly, Jian Rong Bing Bao requires individuals to invite others to engage in communication, show their ideas, and exchange minds with each other. Both academic communities and media should build platforms for freedom of thought, and invite various kinds of people to show their ideas and thoughts. Such as in academic meetings about ethical issues on human genome editing, organizers should invite scholars with different perspectives, and different age groups, as well as patients and the public to participate, and provide a chance and time for them to show their minds. Those platforms and people who have power or privilege should help to find obstacles to science and humanity communications, then remove those obstacles, such as language, travel, or technological barrier.

Secondly, Jian Rong Bing Bao requires individuals to reflect on their own ideas and the idea of others with humility. Individual ideas are influenced by their own experiences, and those ideas are contingency and situatedness. The sharing of thoughts and experiences among individuals helps facilitate the refinement of their ideas. Refinement is a process of reflection with humility. First, an individual should think about whether

others' ideas are justified, logical, and solidly argued. Second, an individual should reflect on whether he or she rejects others' ideas or devalues their experience simply because of their social identity or because it contradicts his or her own ideas. Third, an individual should think about what he or she could learn from others' ideas or experiences and refine his or her ideas.

Jian Rong Bing Bao in China's Domestic Debates

Chinese scholars practice Jian Rong Bing Bao in domestic debates. In some areas of life sciences, Chinese scientists have been at the forefront of scientific research, which involves the exploration and revelation of the mysteries of life. In some of those areas, there is a lack of clear ethical rules and legal regulations both in China and around the world, and there are large ethical controversies in the relevant research or applications of technologies.

In China *in vitro* culture of the human embryo is not allowed to proceed beyond 14 days of embryonic development or the approximate time at which the primitive streak appears. With the development of science and technology, the scientist may culture human embryos *in vitro* beyond 14 days (Deglincerti et.al., 2016), and that spark global ethical debates on revisiting the 14-day rule (Appleby & Bredenoord 2018; Cavaliere 2017). As a bioethicist, I have participated in a few meetings referring to the 14-day rule and witnessed the diversity of views within China. Participants in those meetings include scientists, jurists, sociologists, philosophers, and bioethicists, and some of the meetings are held by scientists. Some claim that research on human embryos beyond 14 days can increase knowledge of embryonic development and contribute to disease treatment and proposed putting the line to 28 days. However, there are considerable controversies regarding whether embryos should be cultured *in vitro* for longer than 14 days, and where the line should be drawn. Some hold that, although the human embryo is not a natural person in Chinese law, we should respect the human embryo in a special manner. They believe human embryos have higher moral status and there should be a line we should cross even though people could learn a lot from research beyond such a line. Most participants agree that revisiting the 14-day rule requires adequate public engagement.

The debate over the 14-day rule reflected Jian Rong Bing Bao. Scientists took the initiative to invite scholars from the humanities and social sciences to discuss cutting-edge technologies and ethical legal and social issues. All the participants could show their ideas freely, and there are controversies in their ideas.

According to my interaction with scientists and the ethical review practices, there is a growing emphasis on ethics and governance among scientists in the biomedical field. Jian Rong Bing Bao requires scientists to be inclusive and open to ethical, social and legal issues. This can facilitate

discussion and collaboration between scientists and humanities, and social sciences scholars to jointly promote responsible research and the good use of sciences and technologies.

JRBB in China's international exchange

International scientific exchange includes not only technical knowledge but also ethics and bio-governance.

I argue that in both areas, Chinese scientists, bioethicists, and other scholars should implement Jian Rong Bing Bao in science and technology exchange. In the dialogue between science and technology, Chinese scholars should continue to hold an open attitude and invite, and welcome scholars from different countries to actively collaborate with Chinese scholars in scientific research. They should pay attention to the different opinions proposed by foreign scholars and accept those well-intentioned and reasonable opinions with an open mind. Scientists should not suppress other scholars from expressing their views because of their own academic status and academic achievements. For Chinese scientists, some of them are forefront in certain areas of natural science and medicine, but that does not mean Chinese scientists have the privilege to stop listening to the comments and opinions of scientists from other countries. Such as scientists' research in embryology, their research is at the global forefront and is not limited to the inclusion of only Chinese scientists, but also proactively invites and incorporates scientists from other countries for international collaborative research. In addition, the collaborations and communications between Chinese scientists and their international counterparts include both science and bio governance, such as the 14-day rule.

Science is without borders, but scientific research activities and technological applications are in different political, cultural, and economic contexts. There are differences between countries not only in political, economic, cultural, and technological development but also in governance across countries. Therefore, Jian Rong Bing Bao can play an important role in exchanging governance on science and technology. The Chinese Academy of Engineering (CAE) has set up a research and consulting program for international collaboration and established a mechanism to invite, encourage and support academicians from countries to participate in the consulting, research, academic activities, and journal construction of the CAE.

On the one hand, China can better absorb and learn from the governance experience of other countries. To be sure, the advanced Western economy has been a prime source of guidance and inspiration. But I hasten to add that China can also learn some from developing countries, rather than judging the value of experiences based on their political or economic status on a global scale. In some of the international dialogues I have participated in, such as

those organized by the Centre for Global Science and Epistemic Justice at the University of Kent, I found views from Southeast Asian and South American scholars illuminating. For example, Professor Abhi Veerakumarasivam and Dr. Natalia Pasternak Taschner shared their experiences regarding science communication in Malaysia and Brazil. I have learned a lot from them, such as how to promote responsible research in their own countries. From my personal experience, except for reading research papers, there is little opportunity for me to communicate and learn from those scholars from developing countries. There is no doubt that China can learn valuable ideas and experiences from developed countries, but that does not mean that valuable ideas and experiences come only from those countries, and China could benefit from an exchange between developing countries. I think China should build a platform and invite scholars not only from developed countries but also those from developing countries, to learn from both, reflect on the governance in China and refine it.

On the other hand, Chinese scholars should share the experience of governance in China with other countries. It may benefit other countries and promote global governance. Science and technology governance in China has changed significantly in recent years, several laws, regulations, and policies have been introduced in recent years to gradually improve the capacity of governance. Chinese scholars should be aware of the governance of science and technology in China. As a bioethicist in China, I do believe that Chinese bioethicists should take their responsibilities to research and build up ethical norms for science and technologies, but that is not all. The voices of scholars, the public, and policymakers from other professions are equally important and should be respected. Especially, scientists are the subject of scientific research, and the government is closely related to their daily work, they are direct stakeholders. In addition, Chinese scientists have more international exchange opportunities than humanities scholars, they can play a more active role in international exchanges and improving global governance.

Conclusion

I believe Jian Rong Bing Bao can be used as a guide for coordinated global actions in the future, it could be key to better innovation, bioeconomy, and bio-governance. Jian Rong Bing Bao is about 'invite others' and 'self-reflection'. It requires us to invite people with different ideas to engage in the exchange, even if they hold conflicting views, help them remove obstacles to exchange, and respect each participant's freedom of expression by giving them equal opportunity. It also requires us to reflect with humility, rather than reject others' ideas or devalue their experience simply because of their

social identity or because it contradicts or their own ideas. It is enlightening for academic dialogue within China and between China and other countries. China has practiced Jian Rong Bing Bao in domestic and international exchange, and that promotes scientific discovery, technological innovation and bioeconomy in China and other countries. I believe that China can do better following Jian Rong Bing Bao. Such as showing the diversity ideas and experiences in China, keeping exchange with developed countries, and increasing exchange with developed countries. Those can help overcome stereotypes about China, developed or developing countries, and ease the conflict between countries.

When I refer to the exchange between China and other countries under Jian Rong Bing Bao, is not a way of advocating the superiority of Chinese civilization over other civilizations. This exchange and engagement should be based on the premise of equal dialogue with mutual respect. For Chinese scholars, it is important for us to pay attention to ourselves when China is a global leader in certain biomedical fields. China is at the forefront of the world's economy and in some areas of science and technology, those give China a certain amount of power and privilege in global science and technology governance now and in the future. Chinese scholars should follow the principles of Jian Rong Bing Bao, respect for all countries and civilizations, and promote global governance of science and technology.

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Building Responsible Life Sciences in Africa: Observations from an Early-Career Female Scientist

Janet Surum*

Abstract: African Union, the continental body that unites 55 African states, has championed the strategic framework, Agenda 2063 since 2015. The Agenda 2063 spells out a blueprint for transforming Africa, aimed at promoting the quality of life and wellbeing for all citizens through citizen capacity building underpinned by science, technology and innovation, and through building productive and socio-ecologically resilient economies and agriculture (Agenda 2063, 2015, African Union Handbook 2022). Such ambition is impossible without the growth of life sciences in Africa. Despite a widely held conventional view that African countries still lag far behind in scientific development, the tremendous effort that African researchers, civil groups, government and quasi-governmental organizations in Africa have invested in mobilising the development of life science in Africa cannot go unnoticed. I am an early career female scientist who works at the University of Kabianga, Kenya. In this short perspective piece, I want to share some of my personal views about life sciences in Africa based on my experiences working with life scientists as well as the views of my African colleagues. In particular, I hope to demonstrate the often ignored roles female scientists and civil organisations play in developing a fair and sustainable bioeconomy in Africa.

Keywords: Africa, Agenda 2063 Kenya, Translational Research

Shifting Landscape of the Life Sciences in Africa

Similar to many developing countries, one major focus of ‘life sciences’ in Africa is agricultural science. Feed Africa (2019) has celebrated many Africans who continue to make an impact in life sciences in Africa. Most notable is one female scientist Geneticist Dorothy Onyango who runs a laboratory in rural Kenya producing a zero-carbon footprint fertiliser that does not only nourish crops but also creates jobs, food and nutritional security for more than 1100 families in Kenya and Uganda. Onyango says that they are trying to align hardline science with soft science, growing products in laboratories that will affect people’s lives. Horticulturalist Mary Abukutsa-Onyango at the Jomo Kenyatta University of Agriculture and Technology had the opportunities to develop her career at much better resourced institutions outside Africa, however, she chose to stay in Africa as she believes in the saying “using the stick in your hand to kill a snake”. This

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is loosely translated to mean using homegrown solutions to solve Africa's unique problems. Despite a chronic deficient government investment in science, Abukutsa-Onyango has produced home-grown solutions to Africa's food insecurity and malnutrition problem through exploring Africa's rich biodiversity and through the study of African super-foods-a name she gave to African indigenous vegetables. Through a succession of research funding bids, she has also gradually built up an inventory of equipment which has enhanced the research capacity of her laboratory. She was funded by the European Commission for a project "Networking to promote the sustainable production and marketing of indigenous vegetables through urban and peri-urban agriculture in Sub-Saharan Africa-IndigenoVeg (Women in Science, 2022). Perhaps even less known is the fact that a new generation of African researchers is actively exploring space science to work towards the attainment of SDGs. Cynthia Umuhire a space science analyst and the first PhD student in Astronomy and space sciences at Rwanda's college of Science and Technology uses her knowledge to improve natural disaster management and agricultural yields (Mawazo Institute, 2022).

African researchers are making a big effort to catch up in the latest biomedical sciences as well. The African Stem Cell Initiative led by the University of Cape Town has been addressing a critical knowledge gap in brain science by modelling neurological disease in African populations. One needs to be reminded that the importance of such a major endeavour in Africa is not restricted to neuroscience itself. Rather, they almost always have a platform effect which helps the capacity building and knowledge exchange of a critical mass in the African scientific community. The science of genomics is gaining ground in Africa too. The Human Heredity and Health in Africa (H3Africa, 2022) is an initiative involving the National Institutes of Health in the US, the Wellcome Trust and African scientists. It aims to transform research in genomics, bioinformatics and health in Africa by developing infrastructure, resources, training, and ethical guidelines to support a sustainable African research enterprise led by African scientists, for the African people. A Nigerian scientist Segun Fatumo is leading this research. "African genomics is a story that's going to be told more and more by Africans," says Charles Rotimi, a genetic epidemiologist at the U.S. National Human Genome Research Institute (NHGRI) (Pennisi, 2021). The work is beginning to close a wide gap in who benefits from the human genome revolution. The major challenge is that funding for all current projects in H3Africa ended in 2022 which may impede the survival and growth of genomics research in Africa (Pennisi, 2021).

There is an acute awareness among African researchers of applying the latest scientific advancement in a way that helps to mitigate rather than deepen health inequality (Alliance for Science, 2022). Dimakatso Gumede

an African researcher at the Council for Scientific and Industrial Research (CSIR) is one of the handful of people in South Africa who have mastered stem cell reprogramming. She works on creating disease models of the innate immune system to study African unique gene variants that lead to elite controllers that naturally control viral load levels without antiretroviral therapy. Through pluripotent stem cell technology, the CSIR researchers create effective and personalized medication for those who do not respond positively to the drugs that have been distributed to the general African population (CSIR, 2023). Renowned geneticist Ambroise Wonkam, the president of the African Society of Human Genetics is also a champion in promoting genetic research that is dedicated to the understanding of genetic particularities of the African populations, and to the investigation of the clinical responses to prevalent genetic conditions in Africa.

The African pharmaceutical industry is largely undeveloped both in terms of its innovation and manufacturing capacities. Yet perhaps a bigger underlying problem is a lack of training capacity for African researchers to carry out the innovation and production needed. I interviewed Dr Antony Yiaile, a Kenyan pharmacologist and toxicologist. He agrees that in Africa and especially in Kenya, the growth of the pharmaceutical industry is impeded by the lack of infrastructure and especially a lack of opportunities for simulation during training which would amplify real experiences with directed tasks that replicate significant elements of the real world and eventually lead to competent professionals. When he studied health sciences at Kenyatta University seven years ago, he did his laboratory work at a veterinary lab as opposed to a laboratory for clinical research. This was not an uncommon training experience among biomedical researchers in most African countries but works to the disadvantage of these scientists. He adds that improving infrastructure would encourage many Africans to pursue this field as well as produce more competent healthcare professionals.

The Kenya Community Health Strategy 2020-2025 identified the poor distribution of the workforce and their coverage ratios across the counties (which ranges from as low as 17% to as high as 90%) as the biggest problem in the healthcare sector in Kenya (Kenya Community Health Strategy 2020). In my interview with Dr Calvince Anino, a public health expert in Kenya, I learned that this is a challenge that is not unique to Kenya. African public healthcare system prioritizes reactive care over preventive treatment, despite the fact that much work is being done on active disease surveillance where health care providers provide information about health conditions to the government. He emphasized that, while public health is still a developing field in Africa, there are very good policies in place, but the problem is in their implementation. In his opinion, the political climate has had a significant impact on policy implementation in Kenya because the

politicians influence which policies are prioritized for implementation. He acknowledges that the workforce falls far short of the WHO-recommended health work density ratio per population.

The Mawazo Institute and Bottom-Up Empowerment

The role of nonprofit organizations in Africa in supporting African scientists cannot be overemphasized. In particular, I want to highlight the Mawazo Institute, which I personally benefited from. The Mawazo Institute is a women-led African organisation based in Nairobi, Kenya supporting young African female scientists as they work to find solutions to local and global development challenges. As a Mawazo fellow, I found myself in a space surrounded by life scientists because Mawazo Institute appreciated that life sciences cannot exist without ‘my’ social sciences perspective and that the success of life sciences also lies in understanding human behavior. Besides equipping me with knowledge, practical skills and support for my research, my attitude towards life sciences changed. Having grown up with a negative attitude towards life sciences. As I interacted with fellow women, conducting great researches in the life sciences, I felt I could also do it, and because of this, as an academician, I now encourage girls to take on the field of life sciences.

Dr Mutono Nyamai a Kenyan female data scientist and a Mawazo alumni, trained at the University of Nairobi and did some short courses in her field at the University of Cambridge and in South Africa, is combining applied epidemiological modelling and data analytics to develop prevention and control strategies for infectious diseases in Africa. She has acquired the knowledge to contribute to reducing morbidities caused by diseases that are plaguing the African continent. In my interview with her, she said that the greatest challenge she faced in her training in Kenya was an absence of data models on tropical diseases in the Global South. Now, she has acquired the knowledge to contribute to reducing morbidities caused by diseases that are plaguing the African continent. More importantly, she wants to pass on the support she once received from the fellowship awarded by the Mawazo Institute and from her professors by mentoring upcoming data scientists in Africa. ‘This is something that is close to my heart’ Nyamai said, ‘I want to ensure that we have a bigger pool of qualified data scientists who can improve the quality of life in our continent, I have learned to say no to opportunities that push me away from this goal.’ She says that mentorship, fellowships, collaboration and building capacity would be the best way to boost life sciences in Africa.

The Mawazo Institute also serves as a hub to spread ideas, and to seed dreams by hosting the Nairobi Ideas Exchange podcast which has over 200 subscribers and features Africans who are making an impact with their big

ideas. The weekly podcast which is mostly embraced and attended by over 100 Nairobi city dwellers is currently in its fifth season. African experts in science and policy have come onto the show to share their career paths and their experience with some of the scientific challenges of our time, such as climate change mitigation, ecological conservation, and the impacts of the COVID-19 pandemic on the African continent (Mawazo Institute, 2022). In November 2022, together with other Mawazo fellows and the public, I was an attendee on the live podcast, the future of African cities and I found it to be an engaging and insightful way of presenting scientific findings that make even nonscientists curious to engage and encourage others to pursue careers in the life sciences. In this specific show, there were three guests: Georgie Ndirangu, a Kenyan broadcaster, Just Ivy Africa, a Climate Change & Green Finance Enthusiast, and Mutono Nyamai a life scientist and a Mawazo fellow. Instead of the traditional way of explaining scientific findings, Nyamai repackaged her research in a series of interesting questions that were pitched to the two guests who competed against each other. The session was informal and fun, different from the structured African science class which is led by monologues packed with jargons. The conventional way of discussing science in Africa can also appear to be alienating as it seems that only those who 'get it' are welcome. However, the way Nyamai communicated her research on the podcast demonstrated that science can be fun and relatable. The questions she posed triggered our curiosity, and for those two hours, we were engrossed in the event. In addition, publications by Mawazo Institute have also promoted the dissemination of African Life sciences research in Africa. Together, these communication channels convey the message that Africa is not scientifically asleep. Such a strategy could be adopted in the larger Africa to make science meaningful and inviting. More importantly, such civil organizations help to attach a human face to science, which helps the younger generation of Africans feel life in science is something that is relatable and achievable.

Bioeconomy for the Common Good?

While life sciences are burgeoning in many African countries, there remain challenges for the bioscience and bio-industry to continuously contribute to the common good. To begin with, infrastructure remains a big hurdle for public access to science. Higher education in Africa is underdeveloped and has received little attention in the last two decades. The world's lowest regional average for the relevant age group's access to higher education remains 5%, less than one-fifth of the global average of 25% (Mba 2017 Association of African Universities). Despite efforts by civil organizations to improve education in Africa, women continue to be underrepresented, particularly in science and technology. Females represent less than 30%

of students graduating from STEM fields in Sub-Saharan Africa (Marie-Nelly, 2021). In my opinion, higher education in Africa is characterized by theoretical education while Africa needs practical education to solve its challenges. Further, African higher education leaders need a mindset shift which weigh the cost-benefit of infrastructure and research facility investment not against short-term return, but as a long-term strategic investment.

The imbalanced economic development also casts a shadow on translational research and creates an imbalance in what kind of research should be given the most priority in Africa. The African Union Scientific, Technical and Research Commission (2019) has devised a plan to expand the scope of translational research to interpret laboratory, clinical, and public health research and to speed up the translation of health discoveries into new or improved standards of care for Africa through developing harmonized good clinical practice guidelines for AU Member States, building strong ethical approval systems, the increased government budget for clinical research, promoting private sector investment in clinical research in Africa and building a critical mass of practitioners, (MDs, MSc, PhDs) among others. This is in response to the fact that the majority of useful African clinical research is sitting on the shelves because generally, African researchers are ‘helpless’ when translating research to practice because most findings need funding support as well as goodwill to be implemented. The “homegrown” successes recorded in the fight against the Ebola virus can be attributed to the “translational” research that has been conducted in Africa.

Another point to consider is the tricky balance between commercialisation and the public good. To be sure, Africa will need commercialization to help fund and incentivize biomedical innovations. But it also needs to avoid being driven by market mentality, which, as we’ve seen in many other countries, has resulted in widening health and socio-economic inequality. The African Union Development Agency (AUDA-NEPAD) has been at the forefront of calling for the commercialization of research through a call for African governments to create an enabling policy environment to harness the benefits accruing from agricultural biotechnology, innovation and emerging technologies in order to transform the livelihoods of smallholder farmers in African countries (African Union Development Agency, 2020). Despite this call, the number of researchers who reach the commercialization stage is limited. In recent years, there has been a push in the region to raise awareness about the shift from research to commercialization. This year, I have attended two very informative trainings on research commercialization: one organized by the University of Kabianga and another by Mawazo Institute jointly with Victoria Ventures, and from my perspective as a researcher, it changes the narrative from conducting research to solve problems to how

can I benefit from my research? I think the emphasis should be on, after solving the problem, how can I benefit from my research? In my opinion, if we do not remain focused on the goal of “bringing solutions to Africa,” what will be promoted in the near future may not be life sciences for the common good, but rather as an additional source of income.

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2. Manuscripts should be prepared using double spacing. The text of manuscripts should not ordinarily exceed 7,000 words. Manuscripts should contain a 200 word abstract, and key words up to six.
3. Use 's' in '-ise' '-isation' words; e.g., 'civilise', 'organisation'. Use British spellings rather than American spellings. Thus, 'labour' not 'labor'.
4. Use figures (rather than word) for quantities and exact measurements including percentages (2 per cent, 3 km, 36 years old, etc.). In general descriptions, numbers below 10 should be spelt out in words. Use thousands, millions, billions, not lakhs and crores. Use fuller forms for numbers and dates— for example 1980-88, pp. 200-202 and pp. 178-84.
5. Specific dates should be cited in the form June 2, 2004. Decades and centuries may be spelt out, for example 'the eighties', 'the twentieth century', etc.

References: A list of references cited in the paper and prepared as per the style specified below should be appended at the end of the paper. References must be typed in double space, and should be arranged in alphabetical order by the surname of the first author. In case more than one work by the same author(s) is cited, then arrange them chronologically by year of publication.

All references should be embedded in the text in the anthropological style—for example '(Hirschman 1961)' or '(Lakshman 1989:125)' (Note: Page numbers in the text are necessary only if the cited portion is a direct quote).

Citation should be first alphabetical and then chronological—for example 'Rao 1999a, 1999b'.

More than one reference of the same date for one author should be cited as 'Shand 1999a, 1999b'.

The following examples illustrate the detailed style of referencing:

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World Health Organisation. 2000. "Development of National Policy on Traditional Medicine". Retrieved on March 31, 2011 from <http://www.wpro.who.int/sites/trm/documents/Development+of+National+Policy+on+Traditional+Medicine.htm>

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This special issue ‘Bioeconomy for the Common Good’ has articles that discuss many issues in this theme. The articles discuss inter alia, bio-sovereignty, fairness and bioeconomy, traditional knowledge, biotechnology in Brazil, Stem Cell Research, relevance of an idea from China for global bioethics, treatments for ageing and health equity, and, responsible life sciences in Africa. Read together they draw our attention to the need for questioning our assumptions on bioeconomy and the role of technology and ethics in furthering bioeconomy. Instead of providing easy answers they help us to critically think on bioeconomy and ideas like bio-sovereignty.



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