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ORIGINAL ARTICLE

Harnessing the value of human bodily material: a bioconstitutional analysis

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Abstract

Human tissues and cells are now recognized as an important source of health and wealth. As such, public authorities have assumed responsibility for regulating their procurement, storage and use. Looking at the interactions between law and life through the lens of 'bioconstitutionalism', we specifically ask how human bodily material (HBM) is regulated and explore the resulting changing relationships between citizens, public authorities and researchers in Belgium, a country where the pharmaceutical industry weighs heavily in terms of employment and economic growth. We examine the regulation of HBM and show how the Belgian bioconstitutional order increasingly promotes research by facilitating the availability and use of HBM in the hope that this will fuel the engine of innovation, employment, and economic growth. We argue that this represents a turnaround from traditional conceptions of biological citizenship, as the state's demand that its citizens donate their HBM for research is reinforced. We emphasize that what it means to be "altruistic" is being reshaped within a new moral economy of donation, without a clear recognition of this reshaping: while citizens are crucial contributors to the development of the bioeconomy, they are excluded from participating in the governance of how this bioeconomy develops.

Keywords Human bodily material · Bioconstitutionalism · Biocitizenship · Biovalue

Introduction

The story of Henrietta Lacks and the HeLa cell line is now well known (Landecker 2010; Skloot 2010) and is deeply intertwined with that of modern medicine and its growing capacity to harness 'biovalue' (Waldby 2000), i.e. the vitality of human

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body parts, to contribute to public health and generate private profits (Aarden 2021). However, since this controversial exploitation of human bodily material (HBM) taken from a sick and racialized woman without her formal consent or knowledge, the development of tissue-engineering products and the progressive use of human instead of animal tissues by pharmaceutical companies to test new medical products have greatly developed, constituting the backbone of regenerative medicine. That process took place in parallel with efforts to deal with new ethical issues such as those relating to the informed consent of donors, the retribution for the donation, the conditions of circulation of HBM, as well as the degree of autonomy of scientific research and the potential conflicts with commercial applications.

To address the issues surrounding the collection, dissemination, and use of HBM, public authorities have had to regulate the political economy of health (Novas 2006; Rose and Novas 2004) to deal with new biological entities, research practices, and the resulting economic and health opportunities and promises. In this article, we focus on the case of Belgium, a country where the pharmaceutical industry weighs heavily in terms of employment and economic growth. Since the 1980s, Belgium has continuously developed policy strategies, both at the federal and regional level, to develop strong and competitive biotechnology clusters. In doing so, the country gradually established itself as an "international medical biotechnology region", and a growing number of biotechnology companies emerged and developed (Segers 2016).

The history of biotechnology in Belgium has evolved in line with a perceived need for profound economic transformation, which the pharmaceutical industry has come to embody more than any other sector since the collapse of the steel industry that had dominated the country's economy between the end of the nineteenth century and the 1960s. As the steel industry declined, Belgium became a pioneer in organ transplantation, which began in the early 1960s (Sholz 2020, p. 7) and continued to develop for over two decades before the first major legislation was passed. In 1986, new legislation on organ donation changed the bioethical standard from informed consent to presumed consent by creating an opt-out system, thereby increasing the body material available to save more human lives. Historically, an impressive increase in organ donation was observed after the introduction of presumed consent (Arshad et al. 2019, p. 1458). Belgium was also the first country in the world to set up a computerized network in 1987 that allows citizens to register their objections to the donation of their organs and tissues after death. Today, although opt-out systems for post-mortem donation of HBM are found in about half of OECD countries, Belgium has one of the highest deceased donor rates (Arshad et al. 2019),[1] making it "interesting for brokers and corporate actors to get access to human tissue material for processing into highly profitable products" (Pirnay et al. 2015, p. 561).

Drawing on contributions from science and technology studies (STS) and political economy, our analysis highlights the constant overlap between the legal and

[1] Belgium presents the third highest deceased donation rate (behind Spain and Portugal) and the fourth highest transplant activity rate (behind the US, Spain, and France) in OECD countries.

biomedical frameworks for exploiting the biovalue of HBM, as well as a historical continuity in which the law provides the same rules for the removal of organs and other elements of the human body after a person's death, regardless of whether the aim is to save human lives or to contribute to the progress of biomedical research. We question this "logical continuation of a long-standing tradition of donating HBM" in Belgium (Lalova et al. 2021, p. 205) and we argue that it takes a new turn in the face of projects linked to far-reaching economic transformations that strengthen the state's claims on its citizens to donate their HBM, reversing conventional conceptions of biological citizenship. These conventional conceptions take into account claims for rights and recognition that are made on a biological basis, such as shared genetic status or disease state. While scholarship on biological citizenship does not ignore how inequalities may be enhanced by the hegemony of biomedical frameworks, the emphasis is often put on the production of new identities, expertise, and hope. It has been argued that this notion potentially eclipses other forms of solidarity such as national identity, labor organizing, and party politics (see Mulligan 2017 for a general presentation of the concept and an overview of these critiques). We add to these debates that biological citizenship is increasingly characterized by an economic dimension which combines different forms of hope: that of developing new therapeutic solutions and new (bio)technological markets in declining industrial landscapes.

In this paper, we ask the following questions: how has human bodily material been regulated in Belgium, and what relationships between citizens, public authorities, and biomedical researchers are consequently performed? To explore these questions, we first start by outlining our conceptual approach, locating the regulated political economy of health within the progressive acceleration of legal and biomedical practices to harness biovalue from HBM since the turn of the 2000s. Informed by the analytical perspectives of 'bioconstitutionalism', we carried out an abductive analysis (Tavory and Timmermans 2014; Thompson 2022), starting with the hypothesis that the ever-increasing importance of health and wealth value of HBM has changed the position of citizens and their bodies *vis-à-vis* the state and its regulations. While some of the literature on bioconstitutionalism had already begun to incorporate dimensions of political economy, it is less common to see the more general arguments of bioconstitutionalism applied to specific cases, where the constitution and configuration of biovalue owe as much to law in the broad sense as it does to micro-practices and management operations (e.g. consent provisions and requirements).

The double movement between theoretical and empirical considerations allowed us to examine the modalities by which citizens' bodies were positioned in relation to the state over time. In Belgium, the legal framework has attempted to strike a balance between often conflicting aims: to ensure the non-commodification of the human body and to place as few restrictions as possible on research and technological development using HBM. In the empirical part of the paper, we zoom in on three types of regulatory action on HBM where the tensions between these goals are the most visible: the regulation of procurement, with a focus on donor consent; the regulation of storage, with a focus on R&D biobanks as infrastructures; and the regulation of use, with a focus on the internal dynamics through which the Federal

Agency for Medicines and Health Products (FAMHP) has evolved as the legally competent authority to regulate the use of HBM. We show that the balance between non-commodification and freedom for research is increasingly tipping in the direction of promoting research by facilitating the availability and use of HBM in the hope that it will fuel the engine of innovation and thus employment and economic growth. We stress that this evolution comes at the expense of protecting both the citizen-donor (through relaxed consent requirements) and the citizen-patient (by prioritizing resources to regulate, control, and promote biomedical research applications of HBM rather than therapeutic ones).

In the discussion section, we emphasize that the notion of 'altruism' is being reshaped within a new moral economy of donation without a clear recognition of this re-shaping. As a result, the biocitizen, who through his original gift of HBM now embodies the necessary precondition for the expected developments in the medical bioeconomy to unfold, is both required to contribute to research and kept at a distance from how this contribution is used and regulated. In some ways, our findings are in line with Hoeyer's call for social scientists to move beyond moral critiques of commodification and "engage more closely with the intricacies of the exchange systems" (Hoeyer 2007, p. 344) established around tradable body parts that are considered "beyond commerce" but nevertheless participate in the co-production of humanness and markets (Hoeyer 2009). Our analysis additionally emphasizes the interwoven process of legal and technoscientific ordering as what makes HBM tradable. We conclude that the exploration of the intricacies of HBM exchange systems must include a detailed analysis of the legal language in its very particular way of encoding what may be subject to a logic of appropriation from a therapeutic or economic perspective, as well as an appreciation of the situated character of case studies such as the one we propose.

Theorizing the regulation of the political economy of health

The body and vitality of individual and collective subjects have long had a value, both economic and political (Rose and Novas 2004). Since the nineteenth century, preserving and enhancing this value has become a matter of state, and public authorities committed themselves to preserve, protect, and enhance the biological capital of their populations. This disciplining of body parts and its integration into political and economic processes has been remarkably studied using Michel Foucault's influential concepts of biopower and biopolitics. Beyond the state governance of the lives and bodies of consenting subjects, some authors have placed increasing hope in the self-management of well-informed, responsible citizens in the face of new developments in biology and biotechnology (Lemke 2004; Rabeharisoa and Callon 2004; Rose 2001). Indeed, the scope for new forms of biological associations based on shared biological characteristics in collectives such as patient associations, disease advocacy organizations, and self-help groups has been shaped by concepts such as 'biosociality' (Rabinow 2005) or 'biological citizenship' (Petryna 2002; Rose 2006; Rose and Novas 2004).

In addition to state actors, researchers and private companies also play a key role in producing the services and pharmaceutical products that are expected to simultaneously generate both private profit and public good. Due to advancements in the fields of genetics and neuroscience, many potentialities of life itself into a source of value creation were realized at the turn of the millennium, such as the unique capacity of embryonic stem cells to renew themselves perhaps indefinitely, and to differentiate into other cells, with the hope that they could eventually be injected into different patients. This led to the development of a "regulated political economy of health", which included relationships between the state apparatus, scientific and medical knowledge, the operations of commercial enterprises, and the consumption of health-related goods by individuals (Rose and Novas 2004).

Medical sociologist Catherine Waldby (2000) coined the term 'biovalue' to refer to the ways in which the bodies and tissues derived from the dead are employed for the preservation and enhancement of the health and vitality of the living. Building on her work, Rose and Novas (2004) suggested that one can analyze biovalue as concerned with the generation of both wealth and health. First, biovalue refers to the ways in which modern biomedicine produces economic value by making the depths of the body visible, understandable, calculable, and open to molecular intervention. In many ways, what the life sciences are doing is a kind of "flattening" of the body's essential functions. For them, it not only makes it possible for these "surfaces" to be biologically comparable to one another, it also makes it possible for them to be incorporated into processes of monetary or social accumulation. Second, biovalue refers to the ways in which the manipulation of life creates value in terms of improved health. For the authors, attempts to manufacture health and vitality from blood and tissue samples taken from the living and the dead add another layer to current biovalue. The promotion of health and vitality is, therefore, not directed only at afflicted people but, potentially, at every citizen.

The dynamics identified by Waldby and Rose and Novas at the turn of the 2000s accelerated with discourses and promises surrounding the development of human tissue-based therapies. For instance, tissue engineering techniques are based on the heady promise of replacing the self with the self by isolating and extracting adult stem cells to repair damaged tissues (whether one's own in the case of autologous treatment or another human in the case of allogeneic treatment) or in vitro fertilization programs based on the donation of 'spare' embryos. Often labelled "innovative" or "advanced", these therapies are presented as having the potential to "increase therapeutic options in a range of indication areas, from cancer to fertility, fomenting a market revolution in the approach to treat almost all diseases" (Morrow et al. 2017, p. 1; see also Kamenova & Caulfield 2015).

While the development of such advanced therapies is considered urgent, there are also challenges that must be overcome before their potential can be realized. A "necessary translation" is needed to move new health therapies from research to the clinic and to the market: 'translational medicine' has become a discipline in its own right, linked to a broader dynamic of doing research more productively (Pfotenhauer and Jasanoff 2017), and thus giving new urgency to the expectation that research on health and disease will produce socially and economically useful results (Heathman et al. 2015). The discourse of translation does not only refer to the internal

organization of science, but "combines a broader imaginary of the promises of biomedical technology with the desire to restructure political and social spaces" (Aarden et al. 2021, p. 2).

To grasp the interplay between biovalue, citizenship, and the restructuration of political spaces, we turn to additional theoretical contributions that, under the rubric of 'bioconstitutionalism', explore "the full range of sites and processes of in which individuals work out their biopolitical relationships with the institutions that regulate them" (Jasanoff 2011, p. 10). Through their shared grounding in Foucaldian thought, proponents of biosociality/biocitizenship share with proponents of bioconstitutionalism the idea that "radical shifts in the biological representation of life […] entail far-reaching re-orderings in our imagination of the state's life-preserving and life-enhancing functions – in effect, a repositioning of human bodies and selves in relation to the state's legal, political and moral apparatus" (Jasanoff 2011, p. 4). Proponents of bioconstitutionalism, however, place law at the forefront of the analysis, arguing that biotechnological advances have constitutional implications that go well beyond judicial interpretation of formal legal documents and include not only written rules and opinions, but also the institutional practices that make up a constitutional order (Hurlbut et al. 2020; Jasanoff 2011; Jasanoff and Metzler 2020). Beyond simply tracing the (ir)regularities of legal rule-making, as if the law were necessarily lagging behind technoscientific change, the analytics of bioconstitutionalism allows for the study of the mutual shaping of biological and legal orders that affects the many ways in which the state is considered legitimate in its attempts to govern the lives of its citizens. Approaching advances in the life sciences through these lenses helps to grasp a "community's shared imaginary of what constitutes lawful governance, and more particularly what modes of reasoning, judgment, and rule are proper and legitimate in a well-ordered state" (Hurlbut et al. 2020, p. 282).

However, with some exceptions (Sunder Rajan 2012, 2011), a focus on the political economic dimensions of HBM is surprisingly absent from most of the literature on bioconstitutionalism. Yet, in the context of a perceived "translational lag" (Aarden et al. 2021), biomedical research is more and more ascribed important values in terms of both therapeutic advances and economic growth. Political and scientific authorities appear to share public responsibility for the success or failure of this progress. The political economic dimensions of HBM is therefore central to contemporary issues and disputes over the exploitation of the HBM's value.

To address these shortcomings, we consider Pistor (2019) a useful resource to start with. Indeed, she provides a compelling account of how law shapes the distribution of wealth. She argues that capital is made up of two ingredients: an asset—a term she uses broadly to refer to any object, claim, skill, or idea, regardless of its form—and the legal code—which refers to the language that legal institutions combine and recombine in a highly modular way to produce capital. In short, she asserts that once an asset has been legally coded, it is fit to generate wealth for its owner. Since the end of the nineteenth century, Pistor argues, the types of legally coded assets have changed over time (from land, to corporations, to debt, to know-how, to financial derivatives) and will continue to do so, but "the legal devices used to code each of these assets have remained remarkably constant over time" (Pistor 2019, p. 3).

Pistor's work usefully complements the analytical perspectives of bioconstitutionalism by directly linking the process of legal shaping to political-economic issues. But it nevertheless overlooks HBM as a new class of assets. As tissues and cells that can be detached from their bodily existence and acquire various forms of value outside of it (Delvenne et al. 2023), HBM has become an asset that can be transformed into capital through the combined action of technoscientific advances and legal coding. Moreover, in addition to contract law, property law, security law, trust law, corporate law, and bankruptcy law—the very modules through which capital is encoded in Pistor's view–, we argue that biomedical law and its own devices (e.g. material transfer agreements or consent forms) have become formidable weapons for transforming living entities into wealth *and* health.

Case study, data collection and analysis

Empirically, we explore the bioconstitutional order surrounding HBM in one in-depth case study: Belgium. By 'bioconstitutional order', we refer to the product of the interplay between technoscientific and legal processes, forming the foundation for the state's regulation of the exploitation of biovalue. The selection of Belgium as a case study was part of a larger research project to explore multiple value forms of human tissues for cell therapy purposes. By identifying the various actors involved in the process of cell transformation, the interest in tracking the influence of the regulation and control agency was quickly confirmed by our first semi-structured interviews with cell therapy laboratory representatives. In order to explore this issue in detail, we analyzed the three main Belgian laws on the procurement, processing, and use of human tissues, as well as related reviews and comments by legal and bioethical experts (Genicot 2016; Leleu and Genicot 2012; Pirnay et al. 2015; Sterckx and Van Assche 2011):

- the Law of 13 June 1986 on the removal and transplantation of organs (hereafter "Law of 1986"),
- the Law of 20 July 2006 on the establishment and operation of the Federal Agency for Medicines and Health Products (hereafter "Law of 2006"),
- and the Law of 19 December 2008 on the procurement and use of human bodily material for human medical applications or scientific research purposes (hereafter "Law of 2008").

The legal and bioethical analyses of the bioconstitutional order surrounding HBM in Belgium were complemented by semi-structured interviews conducted between 2019 and 2021 with 19 persons who were directly involved in the development of the laws we studied (Parliament $n=1$), who monitored their effective application (Belgian Federal Agency for Medicines and Health Products $n=7$, Belgian National Institute for Health and Disability Insurance $n=1$, European Medicines Agency $n=2$), and who were required to apply them (a university hospital $n=6$, a biotechnology competitiveness cluster $n=1$, Wallonia Brussels Biobank $n=1$). These interviews lasted an average of 1 h 47 min, we transcribed *ad verbatim* and

analyzed thematically (Braun and Clarke 2006). These interviews made it possible to trace the context in which these laws were drafted and negotiated, to understand the control criteria and priorities adopted by the regulatory agency, to identify pre-existing or anticipatory practices adopted within biomedical laboratories to meet legal expectations, and to identify the links between legal requirements and laboratory practices.

Coupled with the analytical perspectives related to the regulation of the political economy of health, in the next section we empirically describe the evolution of legal instruments that regulate the procurement, storage, and use of HBM in Belgium, and how these instruments both shape and are shaped by existing biomedical research practices or envisioned future ones.

The Belgian bioconstitutional order surrounding HBM

There are three key legal developments necessary to understand the recent modifications in the "Belgian bioconstitutional order". The first legal development is the Law of 1986 on organ removal and transplantation, which laid the foundations for changing the conditions of consent and expanding the forms of HBM donation. This Law of 1986 and the changes it made possible formed the legal basis on which the state relied two decades later, when scientific advances in regenerative medicine made it necessary to establish minimum quality and safety requirements for the donation, procurement, testing, processing, preservation, storage and distribution of human cells in the EU. A second important legal evolution in Belgium is the creation, in 2006,[2] of Federal Agency for Medicines and Health Products (FAMHP), the competent authority for the implementation of the (then forthcoming) Law of 2008. The third legal development is the adoption of the Law of 19 December 2008 on the procurement and use of HBM intended for human medical applications or for scientific research purposes.[3]

As a member of parliament who was at the origin of the 2008 law explains, the spirit of the law was first and foremost to guarantee various principles, one of the most important of which was freedom for research:

> Freedom of research, therapeutic freedom, social and economic accessibility, these were our cornerstones. […] We cannot lock up research. To us, we must trust the Faculties of Medicine's and the researchers' ethics. […] So yes, to us, there must be freedom of research, absolute freedom, within the framework that I have just described. The legislator must set the framework, but afterwards, the legislator cannot substitute himself/herself to the academic world, to the researchers. We must listen to what the researchers say, and transpose it into the law to allow them to work under good conditions. (Member of the Parliament, personal interview, December 2020)

[2] The Law of 20 July 2006 on the establishment and functioning of the FAMHP.

[3] As such, the Law of 19 December 2008 implemented the EU Directive 2004/23/EC.

At the same time, the protection of the donor was also important, as expressed by a member of the FAMHP:

> We try not to block stakeholders, without losing sight on the importance of protecting the donor and bioethics principles. I think we try to do both, also by systematically inviting ethics committees, practitioners, to avoid going too far, to avoid imposing disproportionate constraints, but also to avoid not being sufficiently constraining. (FAMHP member, personal interview, February 2021)

In this perspective, the donor becomes both a citizen to be defended against a potential willingness to go "too far" on the part of researchers, and a person whose bodily material is considered central to the perceived urgency of developing new therapies and medical products. As we develop throughout the paper, this has significant implications regarding biological citizenship: as citizens-donors become critical providers of research and innovation materials, the state utilizes regulatory measures to encourage HBM donation, thereby paving the way for a new moral economy in which the imperative to donate one's body to save lives is equated with the urgency to contribute to research. Crucial to this perspective is the regulation of how the donor consents to the use that may be made of their bodily material.

Regulating procurement: the extension of the 'opting out' regime for organ donation consent

A first significant change in regulating procurement concerns the way in which the consent regime for HBM donation has been progressively adapted to promote access to human tissues for research purposes. As we mentioned above, the first regulatory basis was the Law of 1986, which applies to the procurement of organs or tissues from a dead person's body, referred to as a "donor", with a view to the transplant of these organs or tissues into the body of another person referred to as a "recipient". Widespread support for the allogenic organ transplantation from the dead developed around a logic of utility and community that views the dead as not harmed by the removal of their organs while the living (and society in general) can benefit from them. This logic was originally supported (and this is still the case in many jurisdictions) by the exclusive validity of 'explicit' consent, where the donor needs to have 'opted-in' to becoming a donor (Prabhu 2019; Rosenblum et al. 2012).

In Belgium, the law of 1986 introduced the 'opting out' system as a means of increasing organ availability for therapeutic purposes. This system created a form of consent to donate that is implicit or presumed: the consent is considered effective unless the donor has stated his or her wish *not to donate*. When it was implemented, this system did not give rise to many objections: it was inspired by a concern for public health, for saving human lives in danger, which takes precedence over the violation of physical integrity—obviously less so after death—but also over the moral rights of relatives (Genicot 2016, p. 904).

A second significant change in the consent provisions came with the Law of 19 December 2008, which builds on the existing legal framework but shifts the moral rationales behind the act of donation. A hierarchy of uses is introduced to make the

conditions for donation more flexible, with significant differences depending on the "type" of use proposed for the body material ("primary use" or "secondary use") and on whether the material is "residual" or not.

According to Art. 2/29 of the Law of 2008, "primary use" concerns "any use of the human body material to which the donor has explicitly and specifically consented in the context of the removal", whereas "secondary use" is defined as "any other use of HBM than that to which the donor has explicitly and specifically consented in the context of the removal" (Art. 2/30), such as the use for research. In cases of "secondary use", Art. 20/1 requires that "the donor must be informed […] and his or her explicit written consent must be obtained in advance". Thus, at first sight, the Law seems to prescribe an 'informed consent' (or 'explicit consent') regime for uses of HBM for research purposes. However, three additional provisions complicate the picture.

First, the same provision adds that: "In case it is impossible to ask for consent to the secondary use, or should this question be exceptionally inappropriate, secondary use can take place after an ethics committee in accordance with the Law on experimentation on human beings has issued a positive advice".

Second, if the secondary use is for research purposes only, this consent is "deemed to have been given" unless the donor has expressly objected (Art. 20/2).

Third, the category of "residual" material is introduced and defined as "the part of the body material that is removed with a view to diagnosis or treatment of the donor which, after a sufficient and relevant part is stored for making, refining or completing the diagnosis or treatment of the donor on the basis of new scientific information, is superfluous with regard to these purposes and may thus be destroyed" (Art. 2/33). The 2008 law posits presumed consent for the use of "residual HBM" for purposes of scientific research. Consent for research uses of such material "is presumed to have been given insofar as the donor or a surrogate has not announced her refusal to the doctor responsible for the removal or to the senior doctor of the hospital prior to the initiation of any action with the residual HBM". It is added that: "For the application of that provision, the intended use of the material as well as the possibility for the donor or surrogate to refuse, has to be notified in advance in writing to the donor or surrogate" (Art. 20/2).

These specific legal provisions are important, since residual samples—leftover tissue obtained during a clinical care—are increasingly conceived as an important source of tissue for biobanks (Giesbertz et al. 2012). Residual samples therefore become assets that have value as resources for further research and as property from which rents can be extracted (Birch 2020; Falkenberg and Fochler 2024; Pinel 2021), for instance through the establishment and management of other assets such as database, research staff or scientific reputation.

In summary, under the Law of 2008, HBM from a living donor can be removed for research purposes and made available through the opting-out regime if (1) the material is removed for a first use—for which explicit consent must be obtained—and then used for research purposes as a secondary use—for which consent is deemed to have been given in the absence of explicit objection; (2) the material consists of residues from clinical care, i.e. residual material. This opens a wide door for making HBM available for research purposes and shapes a new

relationship between patients, their bodies, and research. While the Law of 2008 has been described as a compromise between the non-commodification of the human body and the promotion of freedom of research, the provisions described here tend to favor the latter over the former.

These evolutions have been criticized by various legal and bioethical experts. A first set of criticisms concerned the morality of the Law and the balance it seeks to strike between the rights of donors and the freedom of research. Genicot (2016), for example, considered that the provisions governing donor consent favor the need of research over the permanence of one's control over his or her own body, and that "it might not be acceptable that we are now forced, without any other safeguard than an express opposition, to contribute to research and to the progress of science" (p. 905). In fact, to him, through the extension of the opting out system for post-mortem donation, the Law of 2008 tends to equate the objective of saving human lives and the objective of advancing scientific progress, which he sees as morally doubtable. A member of the ethics committee of a Belgian university hospital takes up this critique of the extension of the opting out system:

> Personally, I am utterly shocked… As much as I can understand the tacit/implicit consent for the organ donation, because it is about saving the quality of life of another human, so there is a demand for solidarity which allows, not really to put aside consent completely, but to consider that is has been given tacitly… As much as, here, for research, I am quite uncomfortable. (Belgian university hospital member, personal Interview, December 2020)

Similarly, Sterckx and Van Assche (2011) viewed the establishment of a presumed consent regime for the use of residual HBM for research purposes as "highly problematic" (p. 253). They argued that a "right to refuse" is not enough and that informed consent for the use of biological material for diagnostic or therapeutic purpose cannot be interpreted as an implicit authorization to use the material for research purposes, thereby arguing for an explicit consent regime (p. 253).

Finally, the extension of the opting-out regime also raises another question: how is the right to refuse effectively communicated to potential donors? Here, the practice of notification in hospitals tends to nuance the ethical benefits of the mandatory written notification to the donor of the potential use of his body material. As a member of the FAMHP explains, in practice it is very complicated for a donor to imagine all the research can potentially be done with his or her initial donation, and for how long. Especially since the modalities of the mandatory "written" notification are left to the interpretation of the hospitals, with more or less good practices:

> The problem is that this "in written form" is often interpreted by hospitals as writing somewhere in the hospital brochure that it can happen. I even saw a hospital in Antwerp (…) that had only put up a poster explaining the concept of residual use of HBM. So yes, it opens a very big door [in terms of freedom of research]. (FAMHP member, personal interview, February 2021)

The regulation of procurement is not the only one to open up such a "big door" to freedom of research. To further scrutinize this tendency, we now turn to how HBM can be stored after procurement.

Regulating storage: the setting up and regulation of biobanks as commercial entities

According to the Law of 2008, biobanks perform two types of activities: the storage and the provision of HBM. Their activities are carried out exclusively within the framework of scientific research and cannot be intended for any human application (article 2/27). Moreover, biobanks are the only structures that can be run by a commercial company. This particular point was debated when the Law of 2008 was adopted. It results from a pragmatic position from the legislator, who paid particular attention to the importance of the private pharmaceutical sector in the Belgian economy, as described by a member of Parliament at the origin of the Law:

> Basically, there were biobanks in universities. The question was whether we could open this up to the private sector. The private pharmaceutical sector here in the country is very important in terms of research, in terms of employment, and in terms of general interest. Janssen Pharmaceutica, GSK, these are all strong companies in Belgium, and I'm mentioning these ones, but there are others of course… and then there are start-ups that are coming up. So it's a very interesting high-tech area for the Belgian economy. In terms of positioning, we had to profile Belgian companies, because we no longer produce steel, unfortunately, we no longer produce coal, well, I mean, things that once made the Belgian economy flourish no longer exist, so of course we are looking for niches. (Member of Parliament, personal interview, December 2020)

During our interviews, many analogies were drawn between the role that the steel industry played in the past and the substitution role that the pharmaceutical industry is expected to play in the future. This member of the board of directors of a public–private investment fund offering financial solutions for the creation and growth of biotech companies in the Liège region, a key node in Belgium's biotech cluster, is adamant when it comes to this subject:

> I think [that the pharmaceutical industry could become the new steel industry] if we're dynamic. Because we live in a world where our economies are stagnating, there's no natural growth. It's clear that we won't be exploiting [natural] resources for much longer, but we still have a specificity in Western Europe, which is the knowledge economy. (Member of a public-private investment fund, November 2021)

Continuing his comparison between the economic importance of the steel industry in the past and that of the life sciences and biotechnology tomorrow, he takes us into the realm of political economy, arguing that "biotechnology represents an external shock, a Keynesian multiplier for the economy, which will allow an exponential

acceleration of growth." His argument is based on three points. The first is the specificity of the doctor compared to the engineer:

> The doctor is a particular innovator, [...] he lives the market permanently: he is face to face with the patient, so he knows the therapeutic and diagnostic arsenal at his disposal, so when he has an idea for an innovation, it is – without him sometimes even realizing it – in the knowledge of the competitive landscape around him. (Member of a public-private investment fund, November 2021)

The second element he highlights is the economic trickle-down that results from investments in the life sciences sector, which should benefit the economy as a whole:

> In Liège alone, pharmaceutical companies have raised around 400 million euros in 2020 – we don't realize it – from all the public subsidies and private fund-raising activities and so on, to finance 3-years business plans. On average, they subcontract about 60%, which means that there are 250 million euros of purchases, investments, consumables, and services, which are a huge exogenous engine for the creation of economic activity. (Member of a public-private investment fund, November 2021)

Finally, the third element that underpins his conviction that Belgium can hope to redeploy its industrial base from life sciences is that the process of bringing products to market makes it more difficult to relocate industrial activities than would be the case in the steel industry.

> In specialty pharmaceuticals, […] the European and American regulatory agencies don't just validate the drug at the end of a clinical trial process, they validate the health product-production unit tandem. And so, if you want to move industrial production, you have to repeat […] the clinical studies that prove that the new production unit is just as effective and safe, and this is so expensive that it is an objective brake on relocation. (Member of a public-private investment fund, November 2021)

In this industrial transformation project, the ability to store HBM in biobanks is a key element for the development of the biotech sector. Indeed, value creation and extraction involve both the flows to and from biobanks and the storage of biological material in these infrastructures, which have become critical intermediaries in contemporary biomedical research (Argudo-Portal and Domènech 2020; Pinel and Svendsen 2021). The door opened to the exploitation of biobanks by companies with commercial purposes once again raises issues related to the commercialization of HBM. According to the same MP quoted above, who was nevertheless more hesitant while speaking of this, "compromises must be made", and a limited commercialization is therefore possible:

> ... after all, the commercialization [hesitates] is basically limited, and therefore it is acceptable. We are not in human trafficking […], it's very specific, it's research, it's the reproduction of cells in [scientifically controlled] conditions […] So, we are in an area that is extremely regulated, difficult to implement without significant human resources, significant financial resources, etc., so is

> that a sufficient guarantee? For me, so far, yes. Does it apply to everything? No, not necessarily. But these are compromises that must be made. Compromises that are not necessarily political. Yes, there is a political dimension, but it is also a compromise with reality. (Member of Parliament, personal interview, December 2020).

This position is shared within the FAMHP interviewees. As one of its members explains, the Agency develops an approach that is conceived as "neutral" regarding the regulation of biobanks:

> As far as the material for biobanks is concerned, I think that the FAMHP tries [...] to remain a bit more neutral. Not necessarily to avoid conflict with the sector, but because we believe that our role is first and foremost to protect the rights of the donor. And, finally, public health is less important in the context of biobanks because public health is not affected by the quality of the material that is stored in the biobank. [...] In any case, the basic idea for biobanks is that we have the least restrictive legal framework possible because it does not really have an impact on public health. (FAMHP member, personal interview, February 2021)

As expressed in this quote, the fact that public health is considered to be only marginally affected by the storage of HBM in biobanks makes it possible to consider a much more flexible regulation of the latter's activities. This perceived limited impact on public health, because HBM stored in biobanks are not intended for healthcare, justifies a certain degree of openness about the actors who can access the right to store and use such material in these infrastructures. Again, a large degree of freedom (being "as least restrictive as possible") is devoted to the storage and provision of HBM for research purposes, including within private commercial companies.

Although this approach may be considered "neutral", it implies political choices regarding the different values and interests to be prioritized to promote the realization of the therapeutic and economic value of HBM by creating the conditions for a large availability of tissues to research actors. The importance of the issues at stake—the development of the pharmaceutical sector in a competitive context where industrial projects are needed more than ever—seems to call for a general mobilization, and the state intends to do everything in its regulatory power to protect public health without hindering commercial projects. As we will see in the following section, these choices are also visible in the asymmetries of priorities within the public institution in charge of regulating the application of the legal framework, the FAMHP.

Regulating use: the asymmetry of resources and priorities at the regulatory agency

The Federal Agency for Medicines and Health Products is a public interest organization with legal personality that was created by the Law of 20 July 2006. The FAMHP's mission includes ensuring the quality, safety, and efficacy of drugs for

human consumption, including raw materials such as HBM used in the preparation and manufacture of drugs.

During our interviews, members of the FAMHP repeatedly pointed out the difficulty for the agency in striking a balance between ensuring the non-commodification of HBM and promoting freedom for research and innovation. For example, one interviewee explains that the agency is often criticized by industrial stakeholders for the fact that the implemented regulations are too restrictive and that they risk "slowing down innovation", "stifling scientific research", or even "making Belgium less interesting, less competitive in the European context". (FAMHP member, Personal interview, February 2021).

There is an internal critique of the asymmetry of priorities within the FAMHP and how its missions have evolved over time, leading to an increased focus on promoting innovation in the biomedical sector. In fact, several interviewees emphasized that the agency is generally eager to listen to its stakeholders, especially regarding the freedom they should have in terms of scientific research. Stakeholders have various channels to make their voices heard: they can be represented on the various expert committees of the FAMHP, or they can contact the cabinet of the minister in charge directly.

Looking more closely at who these stakeholders are, they are quite diverse: they range from large pharmaceutical companies, university hospitals, "peripheral" hospitals, small private laboratories, and so on. The ability of these different stakeholders to make their voices heard differs widely. According to one interviewee, the "peripheral" hospitals and laboratories are the least heard, while the pharmaceutical sector and university hospitals fare better. This interviewee particularly emphasized the important weight of *Pharma.be*, the general association of the pharmaceutical industry, which is very well organized and has easy access to the FAMPH (Personal interview, February 2021). These differences between stakeholders are reinforced by the actions of politicians, especially the cabinet in charge of Health. In this respect, the previous Minister of Public Health[4] and her cabinet were described by members of the FAMHP as particularly attentive to the pharmaceutical industry in order to maintain Belgium's competitiveness:

> I have the impression that [the Minister's] political ideology has also influenced the way we work with the HBM (...) My personal feeling is that yes, it was easy for the industry to ask questions to the [Minister's] cabinet (...) it was easier to convince [the Minister and the] cabinet that, for example, Belgium's competitive position was in danger. (FAMHP member, Personal interview, February 2021).

Another respondent summarizes the situation as follows: "Politics is everywhere in the Agency, and so is industry" (FAMHP member, Personal interview, February 2021).

[4] At the time we conducted most of our interviews, a new Minister of Public Health was in place since a few months (starting from October 2020). When speaking of "the Minister", our interviewees refer to the previous one, which was in place from October 2014 to October 2020, Maggie De Block.

In terms of the structure of the Agency, the regulation of the HBM is scattered across different directorates and units. A coordination of HBM for therapeutic purposes has been established, but its activities have remained very limited, and few resources have been allocated to it. In addition, there are very few staff working on this specific issue within the FAMHP. At the time of our fieldwork, there were only three dedicated people: a lawyer working on HBM, an inspector for all the French-speaking infrastructures authorized to store HBM for therapeutic purposes, and a medical expert on biomedical issues related to HBM.

In contrast to the limited resources allocated to therapeutic applications of HBM, the FAMHP is devoting significant resources to support its use for research and development (R&D) purposes. An example is the establishment of the National Innovation Office (NIO) in May 2017, with the specific goal of promoting and supporting innovation in pharmaceutical R&D. The NIO is the latest evolution of the Scientific Advice-Technical and Knowledge Management Unit, which was established in 2009 with the aim of "facilitating and accelerating clinical research and innovative drug development." According to a staff member, the NIO is intended to be an "innovation window", born out of the "growing need for scientific and regulatory advice in the development of innovative medicines" (Personal interview, February 2021). The NIO provides several services to drug developers: scientific, technical, and regulatory advice[5]; informal meetings with project leaders to guide projects early enough to increase the success rates; and business pipeline and portfolio meetings. The goal of these activities is to guide the development of innovative medicines to increase the success rate when the project leader submits a marketing application.

From 2015 onwards, the FAMHP's remit was gradually expanded to include greater support for innovation in the pharmaceutical sector. In addition to the creation of the NIO, in this period the Agency became a formal member of the European Innovation Network, which is coordinated by the European Medicines Agency (EMA) and the Head of Medicines Agency (HMA).[6] This network aims to strengthen collaboration at the European level to support innovation in medicines. In 2016, the FAMHP also became a member of BioWin, the Walloon competitiveness cluster in health biotechnologies. One NIO staff member links this extension of the Agency's missions to a broader context of the translation of innovative therapies (Personal interview, February 2021). It was also during this period that the previous Minister of Public Health (2014–2020) took office and provided "significant political support", by pushing for the "signing of a pact with industry to stimulate innovation and research" in the biomedical field (FAMHP member, Personal interview, February 2021).

[5] These notices are not free of charge. The price is fixed. There are possibilities of reductions: zero fee policy if the clinical study is conducted within two years in Belgium; 60% reduction if it is a non-profit stakeholder. According to our interviews, most requests for advice are submitted by large pharmaceutical companies, followed by small and medium-sized enterprises. Hospitals and the healthcare sector submit very few requests.

[6] The Head of Medicines Agencies is a network composed of the Directors of the European national competent authorities (e.g. FAMHP).

As a result, according to one FAMHP employee, "the therapeutic use of HBM is not a priority at all within the agency […] the only priority around HBM is research, the biobanks. The other structures are forgotten" (Personal interview, February 2021). This echoes the perception of another employee, who believes that "the therapeutic application of HBM in hospitals is a bit of a poor relation of the sector". This staff member explained that anything related to HBM for therapeutic purposes receives very little recognition and resources within the FAMHP: "We are 'health products' within a 'medicines' agency", implying that the name of the Agency itself is misleading and that the focus is more on one of its components more than the other (Personal interview, February 2021). This situation is described as highly problematic because "the approach is different between industry and hospitals. For the former, it is the money, and for the latter, it is the patient" (Personal interview, February 2021).

The distortion of attention and resources in favor of research and industry is therefore, according to these FAMHP members, to the detriment of the protection of the donor and the patient. It has concrete implications: it limits the capacity to adequately ensure the inspection of establishments that manipulate HBM for therapeutic purposes (before this material is substantially modified and considered a medicine), or to manage the notification of serious adverse events or reactions in these establishments.

Discussion: keeping citizens at bay in a new moral economy of donation

The analytics of bioconstitutionalism reasserts the central role of law in the study of biotechnological advances, going against the grain of the narrative that suggests that the law systematically lags behind in the normative framing of biomedical advances. Through our empirical analysis, we show that technoscientific advances never emerge in a legal vacuum, but also that the legal already-ness that shapes these emergences constitutes a set of holds that can be seized by state actors to give the desired direction to the government of life.

The trajectory of regulation in the political economy of health is not self-evident and requires the craftmanship and engineering of legal experts who code bodily materials in such a way that they can be turned into assets able to generate scientific, economic, or therapeutic value. As argued by Delvenne et al. (2023) regarding the valuation of blood cells, biomedical practice is characterized by the formation of different types of value in specific scientific and regulatory contexts, which can compete with each other, but also coexist in specific (bioconstitutional) arrangements. The creation and extraction of value are also closely linked with assetization processes (Falkenberg and Fochler 2024; Pinel 2021), but it turns out that the forms of value and assetization that result are not equally significant. In the case we studied, the anticipated future returns from controlling or owning HBM as assets that are temporarily stored in biobanks are becoming more economic than therapeutic.

In Belgium, the milestones that made it possible to implement the European directives on HBM were taken up thanks to the revival and updating of what had

been decided almost 30 years earlier, when organs from deceased patients were made available to save more human lives. Today, a donation of HBM quickly becomes embedded in a network of interests that brings together multiple actors with different goals: from doctors who need biomaterial for therapeutic purposes, to scientists who need raw material for their research, to politicians who want to consolidate a biotech cluster, to industrial actors who want to develop commercialized medicines based on HBM. At the confluence of these different interests, the idea of donation, the purposes it should serve and the way it should be organized have been modified by the Law of 2008, notably through the extension of the opting-out system, which "frees" the possibility of donation for research purposes from the imperative of explicit consent in several cases (e.g. secondary use, residual material).

In the Belgian bioconstitutional order surrounding HBM, the balance between non-commodification of the human body and freedom for research is often tipped in favour of research, as it is seen as a backbone of economic growth through innovation and development of private companies in the country. A new "moral contract" is emerging between citizens and the State regarding the procurement and use of HBM which, as we noted, has important implications in terms of biological citizenship. Whereas in the past this contract revolved around the incentive to donate biological gifts such as blood or organs to save lives, today citizens are invited to donate bodily material to advance scientific research, both public and private. As a former stakeholder in a biomedical health cluster puts it, citizen donors are faced with an increasingly clear prescription: to make part of their body available to "improve Science, with a capital S" (personal interview, May 2021).

As noted by several interviewees, these changes are based on an evolving conception of what is considered 'altruistic' in the bioeconomy. Whereas altruism was previously coded in terms of donating to save the life of another human being—in the case of post-mortem organ donation—it has now been extended to include a moral duty to contribute to research and innovation. In other words, a new scientific and economic imperative is emerging that replaces the moral imperative to donate one's body to save lives with the urgency to contribute to research, leading to a profound repositioning of citizens in relation to the state, scientific research, and economic development. Indeed, current opt-out registers do not allow a person to differentiate between the use of their organs and that of any other body material. Even if people became aware of the Act of 2008, their only choice is between opting out of *all* types of donations, including for non-commercial organ transplantation, or opting out of *none* (Pirnay et al. 2015, p. 562, original emphasis).

In our fieldwork, even those actors who are a priori in favor of such a new "moral contract" to provide HBM for the advancement of scientific research are ambivalent about the opting-out system and how it is organized in practice. For instance, one interviewee acknowledges the benefits of the opting-out system in terms of making HBM more easily available in biobanks, which has important advantages in terms of Belgium's competitiveness on the global scene:

> *Interviewer*: Because potentially, if we take away the opt-out and we go through stricter consent processes, then it gets complicated?

> *Interviewee*: It gets complicated! Come on, Belgium is, I think, the third or fourth country in Europe with the highest concentration of structures that play with HBM. And not necessarily biobanks, I'm talking about production, facilities, intermediaries and biobanks. So why should we close the doors and lock all this when the market is there? Europe is open, Belgium is now becoming a rather large platform compared to the whole of Europe. (Personal interview, May 2021).

However, the same person also criticizes the opting-out system and the way in which the right to refuse is often communicated to the potential donor, precisely because it tends to hide from the donor the use that may be made of his or her bodily material. According to him, this approach is based on a representation of the citizen-donor in the eyes of the competent authorities (i.e., governments and FAMHP) as someone who is naturally suspicious of the pharmaceutical industry and the potential commercial applications that could arise from his donation.

In his opinion, the moral contract between the citizen-donor and society should be made more explicit, full information should be provided to the citizen-donor before and after the donation, to make transparent the different uses that could be made and/or have been made of their bodily material, the different actors that have manipulated it:

> I think a good policy would be to be completely transparent in the sense that you must show the patient that the tissue is important. You must show them, for example, that their tissue has been used in this or that project. And how do you do that? Well, simply by sharing the data, by sharing what we have done (Personal interview, May 2021).

Addressing this criticism would require a reconfiguration of the way biobanks are currently governed, and would likely involve modifying the opt-out system to make consent more informed and explicit even before, but also after, HBM donation. However, as the stakeholders we met noted, we are still far from such a dynamic. For now, citizens are largely kept at bay in the new moral economy of donation.

Conclusion

In this paper, we have analyzed the reciprocal influences of legal and technoscientific progress on the regulation of HBM in a particular country, Belgium. The opt-out system, rooted in Belgium's longstanding tradition of organizing the donation of human biological materials, in conjunction with the significance of the pharmaceutical industry in the context of a declining steel industry, presents a uniquely intriguing case study. To answer our first research question, we examined how the "regulated political economy of health" (Rose and Novas 2004) is organized around the procurement, storage, and use of "biovalue" (Waldby 2000) resulting from a donation of HBM. Informed by the analytics of bioconstitutionalism (Jasanoff 2011), which we have taken a step further by exploring the combined impact of the law writ large and the micro-practices that shape biovalue (e.g. consent procedures or

regulatory advice to guide the development of innovative health products), we have scrutinized the role of the state in determining the conditions under which these living entities may be obtained, stored, and used for scientific or therapeutic purposes. We observed that even when the bioethical framework is fully respected (e.g. patients have the right to privacy, autonomy, integrity, dignity), small changes at the intersection of life and law operate a gradual and increasingly clear shift towards greater scientific and commercial exploitation of donated human entities.

In the blooming literature drawing on the notion on asset in law (e.g. Pistor 2019) and STS (e.g. Birch and Muniesa 2020), the focus is often put on intangible assets like patents, not tangible ones like human body parts. This article demonstrates how HBM can become tangible assets, whether via exchanging tissues for life-saving purposes or storing them in biobanks, where the potential for future income is tied to the anticipated economic benefits of biomedical research and first goes through the specific interests of biotech and pharmaceutical companies before any possible socioeconomic or health benefits can arise.

The regulation of HBM in Belgium is characterized by the search for balance between the production of wealth and health. Navigating through our empirical analysis of three types of regulatory action on HBM, we found that the regulatory instruments and practices challenge some of the rules and principles that have constituted the bioconstitutional order to date. While the law enshrines the non-commodification of the human body and the freedom of research, these two principles are no longer placed on an equal footing, as Belgium is increasingly driven by a strong will to support the provision of HBM for scientific research, in the hope of developing biotechnological innovation.

To answer our second research question about the relationships between citizens, public authorities and researchers that the regulation of HBM entails, we focused on the type of biological citizens, i.e. embodied political subjects with rights and duties in relation to the state and biomedical research (Rose and Novas 2004), configured by the Belgian regulation of HBM. Rose and Novas (2004) argued that biological citizenship is not only 'made up' and imposed from above, but reflects a situation in which "an active scientific citizenship is increasingly being enacted, in which individuals themselves play a dynamic role in enhancing their own scientific – especially biomedical – literacy" (p. 13). Subsequent studies on this topic pointed to the importance of patient associations, disease advocacy organizations, and self-help groups in generating new forms of subjectivation and collective action. The focus was on the extension of rights, the emergence of new opportunities for participation and the choice-enhancing possibilities of new genetics, a perspective that was later criticized as overly optimistic (Heinemann and Lemke 2014).

While biocitizenship has often been described as linked to new demands formulated by self-organized citizens on the state, the forms of biocitizenship we observed in this case study show the opposite: because of the imperative to promote the development of new therapies—linked to the hope of both therapeutic solutions and innovative products to be marketed in a vibrant bioeconomy—it is the state that formulates new demands on its citizens. As a result, calls for solidarity have taken on a strong economic dimension: people are being asked to donate their bodily material for research so that the national bioeconomy can flourish.

The bioconstitutional approach adopted in this article demonstrates the need to consider the central role of law in shaping the logic of the appropriation of human body parts to satisfy scientific, therapeutic or economic needs. The evolution of the Belgian bioconstitutional order towards an imbalance between the moral principles previously enshrined in it—the non-commercialization of the human body and freedom of research—should not lead to conclusions that too quickly assume the overwhelming dominance of a universal capitalist logic that would impose itself on everyone and everywhere in the same way. Even within highly structured political and regulatory arenas such as the European Union, there can be great variations in the ways in which directives are implemented and in the legal frameworks relied upon by national authorities, as well as scientific and industrial actors, to enable the circulation of ever more bodily material.

In this respect, how the Belgian bioconstitutional order compares with others in Europe and worldwide is open to further empirical analysis. To the best of our knowledge, no systematic comparison based on various in-depth case studies, such as the one we present here, has yet been carried out. From the few published works that have conducted comparative analysis, we can conclude that the regulation of the procurement, storage, and use of HBM in Belgium is considered "atypical" when compared to other European countries (Lenk and Beier 2012), with the extension of the opting-out system of consent being described as more permissive than the regulation of other European countries.[7] However, further research is needed that goes beyond simply comparing legal texts and instead examines the combination of law and micro-practices, like we have done in this paper. For, as we have shown, the careful study and comparison of the small imbalances generated by the reciprocal shaping of law and technoscientific progress, and what links them to the consolidation of markets based on the production and use of biovalue, can only be undertaken by also appreciating the situated character of the case studies.

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[7] In a comparison of different EU countries with regard to their legislations on the conditions for residual biological materials to be turned into research collections during the procedure of procuring these materials for diagnostic, therapeutic or other non-research purposes, Gefenas et al. (2012) placed Belgium and its presumed consent system (along with The Netherlands, Austria and Iceland) among the most permissive countries.

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