

## Law, Genetics and Genomics: An Unfolding Relationship

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The relationship between genetics/genomics and the legal and ethical landscape has been long and varied, and it is continually evolving. Depending on the moment in history and the specific area involved, this relationship has proven tragic (consider eugenics and the laws it inspired), beneficial (consider the many criminal cases solved through forensic DNA) and promising (consider attempts to regulate emerging gene editing techniques) – but it has never been easy.

The idea to dedicate a Special issue of *BioLaw Journal* to the origins, state of the art and future of this interrelation emerged during an international symposium organised by the Italian Chapter of the International Society of Public Law (ICON-S) in Florence in 2019, addressing the topic of *New Technologies and the Future of Public Law*. A stimulating discussion on the new challenges of genome editing convinced us that trying to bridge between past and present was important in order to better imagine the future. Aware of this issue's challenging and multifaceted nature, we involved outstanding experts who had devoted years of their research

activities to these topics, together with passionate young scholars whose imaginations had more recently been captured by these complexities. Relying on a cross-sectoral approach that embraced – beyond law – medicine, the history of medicine, philosophy and bioethics, we cooperated with interested Authors from different parts of the world (beyond Italy, including Australia, Belgium, Canada, China, France, Hungary, the United Kingdom, Portugal, Qatar, South Africa, Spain, Sweden and the United States), showcasing the global dimension of genetics challenges.

Far from encapsulating the essential features of human nature, genetics is undoubtedly tackling the origins and future development of the very idea of humanity, rooted in history and prospects for evolution. From this consideration, we decided to organise this Special issue on the basis of a timeline moving from traditional concerns towards the most innovative and unexplored issues.

To prepare the field for this discussion, the first part of this Special issue comprises a Forum in which experts share some visions of the most sensitive matters. The points touched upon in this first part of the issue mirror the broader reflections presented thereafter, offering a precious insight into the remainder of the Issue.

The debate is opened by three scientists (Simonato, Verlengia and Barbujani) who offer critical understandings of the potential and risks of genetic knowledge as a complex subject – and of the indispensable need for interdisciplinary debate on its applications.

The following contributions discuss the specificities of genetic information and the dynamics it triggers in different fields. Genetic data's ultra-individual nature, for instance, requires an in-depth consideration of the importance of sharing within the so called “biological group” (Rial-

Editorial



Sebbag). Beyond the clinical setting, sharing also occurs at a different level in the scientific research field, revealing tensions between the “open data agenda” and the protection of traditional privacy standards and confidentiality, along with an ideal of self-determination. These tensions are particularly evident in specific areas of research, such as research on rare diseases (Rothstein), in which a lack of affected individuals to study may compromise research strategies, and shared research protocols are needed beyond different national systems. More generally, the frictions produced by the global dimension of research require the law to rethink itself – sometimes in provocative terms – in order to reconsider its role and assess the importance of spaces dedicated to different instruments, such as sources of soft law or mechanisms of trust and responsibility based, for example, on combined professional discretion and accountability requirements, along with the supervisory role played by institutions such as Institutional Review Boards or ethic committees (Knoppers and Beauvais, Rothstein). An area where these needs are particularly evident is in the application of new gene editing technologies, where procedural questions about how to deliberate and make regulatory decisions play a crucial role (Casabona).

The section closes with a forward-looking philosophical reflection on the concept of *embodiment* between the human and the artificial, with which moving from a biological inheritance to a machine-based future is not a neutral process but, rather, a cultural inheritance of modernity (Calo).

The same timeline that characterises the introductory Forum structures the following part, made of two Sections of essays: “Troubling historical roots and contemporary challenges” and “Views into the future”.

The first Section progresses from the history of genetics (Ampollini) and the dramatic consequences of its misinterpretations of contents by public authorities (Tomasi) to the current challenges stemming from the field’s actual characteristics. In this section, notions of *autonomy* and *privacy*, already presented in the introductory section, re-emerge in specific declinations. First, some reflections are devoted to the clinical field, within which a constitutionally oriented vision must be applied. Accordingly, the concept of *self-determination* and the related instrument of *consent* must confront the fact that a person cannot be understood as an atomistic entity, disconnected from the relationships in which he/she lives. For instance, the configuration of a right not to know “incidental findings”, is articulated not only in terms of *self-determination* but also *solidarity* and *responsibility* (Cozzi). Similarly, the field of newborn screenings’ regulation presents an urgent need for balance between protecting children’s best interests, exercising parental responsibility and the collective interest in preventing serious diseases whose management strongly influences – from a socio-economic perspective – the whole community (Di Costanzo). Moreover, these complex balances and their resulting conflicts find different points of synthesis, depending on their surrounding conditions, which can determine – as in the case of the current Coronavirus disease pandemic – exceptional states that subvert traditional logics (Brownsword and Wale).

The context in which these issues primarily emerge is family relationships, where genetic bonds produce a strong impact. Two papers in this Special issue are devoted to a search for origins. The first of these papers (Agosta) compares the case laws of the European Court of Human Rights and Italian Constitutional Court with regard to cases concerning the search for a

mother's identity. The second of these papers (Busatta and Penasa) is dedicated to the right to know one's genetic origin, its profoundly relational nature and the need to balance it with other competing individual rights, which – according to the concrete context at stake (anonymous birth, gamete donation and surrogacy) – can be traced back to donors, to gestational mothers and even to children themselves (i.e. the right to a safe birth, as in the case of anonymous birth). Other familial issues arising from genetic data shared nature concern the need to communicate potentially relevant information to individuals with a qualified interest. In this context, any processing of genetic data (also under the European General Data Protection Regulation) should be regarded as an exercise of balancing interests which cannot be limited to over-protecting the right to self-determination over data (De Miguel Beriain and Jove).

Very similar approaches, which require overcoming a purely individualistic logic of “closedness”, also emerge in different fields, such as scientific research. This development shows that genetic testing is a “complex and integrated enterprise” which management requires to reinterpret and sometimes transcend existing regulatory instruments (Slokenberga). Samples and data are the most valuable resources to the aims of genetic research, and they are more and more often collected from outside traditional research settings (Shabani), thanks to various online tools and platforms (e.g. electronic health records, mobile health apps, disease registries and patient-generated databases). These instruments, together with the important wide sharing of research materials beyond national borders and at different times, require an in-depth discussion of the challenges associated with data processing's governance and traditional instruments of self-determination,

such as informed consent. As the two examples presented in this part of the Special issue show – one related to a specific national context (Mahomed and Staunton) and the other related to a concrete research project in South Tyrol (Biasiotto, Pramstaller and Mascalzoni) – privacy itself cannot protect participants or properly balance all relevant interests. Especially when the sharing and reuse of samples and data are involved, privacy must be combined with external governance mechanisms to sustain and promote trust and ensure transparency. Not only are privacy and consent under pressure, but so are intellectual property rights; for this reason, the Special issue is enriched by a reflection that assesses possible scenarios for biotech-related patent applications' future, starting with a case-law analysis (Lucchi).

The contents of this Special issue also focus on the use of genetic analysis in the field of criminal investigations. Beyond the problems raised by criminal lawyers, the contributions collected here reflect on the elements emphasised in clinical and scientific research from a different perspective: the links within the family group, which allow the development of sophisticated investigative techniques, from “familial searching” to “forensic genetic genealogy” (Formici), and the need to exchange samples and data at the international level – in this case, for justice purposes (Scaffardi). The challenge is to strike a proper balance between the public interest in security and a rapid, efficient identification of unknown offenders, as well as the dangerous shift towards “genetic surveillance” which jeopardises individual rights.

The issue's second Section, dedicated to the “Views into the future”, considers genetics' ability to shape ourselves and the world around us. The first contribution considers the difficulties of tracing a sharp line between what is “natural”

and what is “synthetic” and the importance of general principles, such as dignity and justice, as well as specific instruments, such as informed consent, which cannot be fully renounced ahead of technological advancements of bioengineering and their circulation in a free market (Đuković). Among the various technologies that can now affect the concept of “naturalness”, a wide-ranging ethical and legal debate surrounds gene editing techniques. In particular, genetic engineering is on the cusp of a transformational change, thanks to CRISPR-Cas9, a tool that allows scientists to alter different organisms’ DNA – including humans – with high speed and precision and at relatively low costs. Two papers in this Issue are specifically dedicated to these techniques and particularly address the importance of a global approach to this topic, which can rely on proper regulation levels, based on human rights law and international law principles (Poli), and on the recourse to innovative instruments, such as deliberative democracy (Ragone). The rising chance of modifying genetic features or selecting individuals on the basis of their genetic makeup – resulting from advances in genetic knowledge – affect parent-child relationships, sparking arguments about intergenerational justice. Regarding these sensitive issues, diverse attitudes and opinions can be shown. The views presented in two of the papers collected in this Special issue seem to occupy the two extremes of this spectrum, but they are actually inextricably linked. On the one hand, one contribution addresses parents’ civil liability *vis-à-vis* claims presented by their children, not only for their actions but also for their omissions (Payán Ellacuría). On the other hand, a strong position favouring gamete selection in order to allow parents to choose non-health-related features is presented and discussed (Raposo).

We decided to place two very different papers sharing a common “take-home” message at the end of this Special issue. This message can be summarised as the importance of a systemic vision in addressing the regulations of genetic/genomic applications. Legal and ethical reflections must understand that no intervention or activity in the realm of genetics can be considered neutral – that interrelations are a fundamental feature of our world. Even choices concerning the smallest insect inhabiting our planet must be carefully weighed because they entail broader considerations that affect all living beings and our entire environment (Annoni and Pievani). Finally, human beings today cannot be considered solitary agents: our biological niche, built on a complex network of relations, requires a consideration of not only other (past, present and future) human beings and animals but also machines (Santosuosso), always expanding our responsibilities.

The picture is inevitably incomplete, but the papers collected in this Special issue offer vivid insights into continually important issues surrounding genetic knowledge – both within and beyond ethico-legal debates.

We thank each contributing Author for their commitment, essential contribution, patience and enthusiasm for this discussion, which aimed to facilitate intergenerational and interdisciplinary encounters. Special thanks are also due to Elena Scalcon and Federica Fortunato, whose assistance and expertise were essential for this Issue’s accurate editing.

*BioLaw Journal* is very attached to the vision of (bio)law that emerges from this collective effort. This law pays attention to the concrete reality which it aims to regulate, and it is up-to-date. It is proportionate, non-invasive, plural and non-value oriented. Finally, it recognises the past

which it encapsulates, and it can adapt to the challenges ahead.

*Editorial*

