



BIOLEGALITIES

Biolegality

A Critical Introduction

Sonja van Wichelen · Marc de Leeuw



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Biocalities

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This interdisciplinary series on *Biolegalities* engages with contemporary challenges and implications of new biotechnologies and biological knowledges in the field of law. Our series aims to open up a broader understanding of biolegality that includes a range of biotechnologies and biological knowledge, expanding into areas of immigration law, trade law, labor law, environmental law, patent law, family law, health law, human rights law, and international law. While the growing scholarship on biopolitics has studied the ways in which such practices are entangled with certain modes of governance and neoliberal economies, their translations, deployments, and reconfigurations in the realm of law or legal practice has been relatively understudied. The main objective of this book series is to provide a venue for the study of the complex and often contested ways in which biotechnologies or biological knowledges are reworked by, with, and against legal knowledge.

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ISSN 3005-0227

ISSN 3005-0235 (electronic)

Biolegalities

ISBN 978-981-99-8748-1

ISBN 978-981-99-8749-8 (eBook)

<https://doi.org/10.1007/978-981-99-8749-8>

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Cover image: The cover image represents cells from Henrietta Lacks, an African American woman who passed away in 1951 from cervical cancer. The HeLa cells encompassed the first human cell line able to reproduce indefinitely and became used in research around the world. After it became known that the cells were collected at the John Hopkins Hospital in Baltimore without consent, debate erupted about ownership of human biological material and the ethical conduct of biomedical research as discussed in Chapter 3 of this book. Title: Scanning electron micrograph of just-divided HeLa cells. Zeiss Merlin HR-SEM. Source: National Institutes of Health (NIH) Date: 17 August 2011, 02:40:59

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The registered company address is: 152 Beach Road, #21-01/04 Gateway East, Singapore 189721, Singapore

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For Luc and Nils

Prologue

One morning in the fall of 2017, during our sabbatical in Berkeley, our 8-year-old son asked what we were writing about. We answered that we were writing a book about law and science. “But law and science aren’t the same things” he replied. “How so?” we asked. “Law is about the rules, and science is about experimenting.” “Well,” we said, “our book is about the rules of experimenting ... and experimenting with the rules.”

In a crude version, our response to him sums up well what we are trying to do in this book. We are bringing together two apparently disparate fields, namely law and biology, to meaningfully engage with some of the most pressing issues in society today: the confrontation between new bioscientific and biotechnological advances, and legality in contemporary societies. These technoscientific advances are rapidly changing society, and law—as one of our defining social institutions—is a key site for the social and cultural translation and mediation of bioscience’s impacts. But law is not usually where we analyze the relationship between science and society. Typical contemporary scholars turn to bioethics when investigating these social changes. Since its conception in the US in the 1970s, bioethics developed into a significant institution in

the Anglo-American world (see 211 in Poland 2005). Nowadays, bioethical committees and working groups are routine, if not required, in any endeavor involving bioscientific experimentation or application. These efforts have made important contributions to jurisprudence and legal practice, leading to substantive changes in the interpretation of common law.

Despite its importance, our call to study biolegality moves us beyond bioethics and its use of expert knowledge to deliberate over and prescribe rules for policy and legal process. Rather than focus on rulemaking by experts, in this book we concentrate on the changing understanding of foundational legal principles precipitated by bioscientific advances and applied technologies. We look, instead, at the *enactment* of ethics through practical legal knowledge, describing the role the practice and purpose of ethics performs in the making of biolegality (Van Wichelen 2019). These are not ideas or reconfigurations of ethical norms brought about by moral philosophers, ethicists, or medical experts, but by a contingent encounter between institutional practices, (trans)national imaginaries, and communal (be)longings. While the book concentrates on legal concepts—property, personhood, parenthood, (collective) identity, and so on—we approach these as social and political objects investigating how, and to what extent, biotechnology rearranges the original premises of law.

One could argue that these investigations fall within the category of biolaw, but even though we engage with legal theory and contemporary jurisprudence, our investigations are instead informed by the anthropology and philosophy of law, focusing more broadly on social ordering, which takes place inside and outside the confines of biolaw. According to some legal scholars, biolaw—which emerged from France in the 1990s—presupposes bioethics and the two are therefore inseparable (Kemp 1998). Dealing with developments in medicine and biotechnology, the field is evolving rapidly and represents a central node in biotechnology's application in society at large. While the book engages with some of the core issues in biolaw, we also draw on scholarship from outside of law to show how scientific and technological knowledge, experience, and legitimacy are performatively constituted through practice rather than through deliberation. Thus our conception of “biolegality” is the product

of a myriad of disciplines, including sociology, anthropology, history, political science, philosophy, cultural studies, and science and technology studies. This diverse scholarship describes legalities, legal consciousness, and knowledge practices as performed by lay individuals, communities, cultures, or nation-states, rather than bioethicists, medical experts, lawyers, and judges *per se*.

The aim of this book, then, is, despite their significance, to step back from bioethics and biolaw and to look at the work of biolegality as the larger social and political field these specialized discourses contribute to but neither transcend nor control. By “legality” we do not refer to its literal meaning that denotes lawfulness or an observance to law. We refer, instead, to the experience and meaning people attach to law as they engage, avoid, or resist it (see p. 335 in Silbey 2005). As we demonstrate, the complexity of opposing narratives and paradoxical situations regarding law and the biosciences strengthens rather than weakens the law as a structure of social action. Our aim is to bring together scholarship in this new field in order to describe how the law surrounding the biosciences at once affects the activities of people and communities and is itself affected by the way people and communities incorporate, oppose, or negotiate new developments in bioscience and biotechnology. We see these narratives as forming new legalities around the idea of nature and biology.

But legality is also about legitimacy. For instance, the formal regulations regarding freezing and banking eggs and semen for research or reproductive purposes (described in Chapter 4) legitimize—i.e. make both lawful and socially acceptable—the temporary storage of biological substance to advance knowledge or create life (see p. 472 in Waldby 2015). Working through the ways people, communities, institutions, markets, and states respond to these new legal particularities, new legitimacies emerge to inform new kinds of politics. In this example, freezing human reproductive material becomes a form of potentiality imbued with hope and fear, but also rights and duties. These rights and duties are entangled with forms of reproductive citizenship (Carroll and Kroløkke 2018) that embrace the values of nuclear family life, romantic couplehood, and genetic progenies nurtured by the state. Biotechnological

legitimacy is thus formed by how institutions adjudicate and sanction the politics of life.

Such politics of life bring our book close to the project of biopolitics, the governance of life processes and populations through the power of authoritative knowledge practices (Lemke 2011, Mills 2017, Rose 2006). Indeed, biopolitical strategies and their inherent relationship to legitimacy are central to our investigation. Nonetheless, our book is also a programmatic intervention in the scholarship on biopolitics, which has often overlooked the explicit realm of law and legality, prioritizing governance and governmentality rather than legitimacy and legality (Fassin 2009, Pottage 1998). Focusing explicitly on law, we demonstrate not only that the law is a fascinating terrain on which to explore biopolitics, but that the study of biolegality introduces a greater complexity to biopolitics. This complexity has much to do with legal form and the rules of engaging the law. While the biosciences and their attendant technologies often reinforce or are appropriated by existing forms and rules, our main contention is that they also disturb, deconstruct, and transform legal form and rule. This creates new conditions for thinking about law, conditions we hope to illuminate in the service of conceptualizing biolegality for future use.

Sonja van Wichelen
Marc de Leeuw

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Acknowledgments

This project began during one sabbatical and was completed during another. Institutional support—both financially and intellectually—was essential to this endeavor. We would like to thank the University of Sydney and the University of New South Wales for providing the means for our sabbatical leaves. In particular, our last sabbatical—during pandemic times—was only possible because of high-level institutional leverage. In 2017 we were based with the Center for the Study of Law and Society (CSLS) at the University of California, Berkeley, and we thank Jonathan Simon and Catherine Albiston for hosting us. Our first ideas were presented to this group, and we are thankful for all the questions and comments we received from the CSLS community. Our time in the Berkeley Hills was marked by our proximity to the places where biotechnology was in the making and where legal cases formed important precedents. It was the hightide of the CRISPR-Cas9 technique and we were fortunate to attend public talks and discussions led by one of its inventors, Jennifer Doudna. It was an exciting time and place to be thinking about the ethics and legalities of emerging biotechnologies.

It took another sabbatical in 2020–2021 to complete this project. This was amid the global COVID-19 pandemic and while Australia was locked out from the rest of the world—and therefore responding well to the threat of contagion—we managed to travel from Sydney to start our Fellowships with the Institute for Advanced Study (IAS) in Princeton, New Jersey. We would like to thank Didier Fassin and Alondra Nelson for inviting us to join their School of Social Science. Even during a pandemic, they managed to sustain intellectual debate and it was such an ironic coincidence that the 2020–2021 seminar focused on “Science and the State,” a topic well-suited to pandemic times. Our thanks go out to Alondra Nelson and Charis Thompson for directing the seminar, whose discussions informed much of the thinking in this book. We also would like to thank all the other scholars of the 2020–2021 cohort, especially Joshua Barkan, Joy Rohde, Thomas Fossen, Magdalena Malecka, Jacob Foster, Leslie Paik, Nusrat Chowdhury, Banu Bargu, Lawrie Balfour, Christo Sims, Diana Graizbord, and Waqar Zaidi for their collegiality and friendship. And a special thanks to Miles Jackson from the School of Historical Studies for his continued support of our biolegalities project.

This project received generous funding and we would like to acknowledge the Institute for Advanced Study—especially the Institute’s Founder Circle Members Deborah Lunder and Alan Ezekowitz. Sonja would also like to acknowledge the Sydney Research Accelerator (SOAR) prize scheme at the University of Sydney, which generously allowed her time away from teaching to write a significant part of the manuscript, and the Sydney Social Sciences and Humanities Advanced Research Centre (SSSHARC) for funding the Biolegality Pup-Up Research Lab, which brought scholars together from across the world to discuss biolegality. Marc would like to thank the UNSW Faculty of Law & Justice for supporting the UNSW Initiative for Biolegalities for several symposia (“The ‘Biological Turn’ in Law: A Critical Appraisal”; “The Seeds of Law: Monsanto, Patents and the Public Good”; and “Natural and Unnatural Threats: Pandemics & the Global Governance of Health and Biosecurity”).

We would like to thank our editors Joshua Pitt and Marion Duval for their relentless support, enthusiasm, and patience in bringing this manuscript to production. Palgrave Macmillan’s advocacy of Science

and Technology Studies is encouraging for the discipline, and their support for bringing the Biolegalities Book Series into existence is a sign of their editorial willingness to take up projects at the margins of conventional disciplines. Ben Stork—our personal editor—meticulously read the whole manuscript and we thank him deeply not only for his highly professional editorial assistance, but also for his very constructive and helpful comments, which have significantly improved the quality and clarity of our manuscript. Thanks to Gopalakrishna from Springer Nature for her immense patience in the final production stage of the manuscript.

Finally, our sons Luc and Nils have endured two transcontinental sabbatical moves and too many talks around this never-ending book. We are proud of their dispositions to tag along and to trust us that—even in times that we were unsure ourselves—things will be okay. This book is dedicated to them.

Praise for *Biolegality*

“*Biolegality* offers a fascinating account of how advances in biotechnology shape our legal institutions and practices while simultaneously creating new ways for communities and societies to relate to biomedical knowledge, including genes, brains, bodies, and babies.

Drawing upon an impressive range of disciplines, they convincingly demonstrate how biotechnological knowledge transforms legal knowledge and entities, reconstructs the biomedical disciplines and nature itself, and shifts the social order. This is a must-read book.”

—Myles W. Jackson, *Albers-Schönberg Professor in the History of Science, Institute for Advanced Study, Princeton, USA*

“*Biolegality. A Critical Introduction* offers an excellent account on the manifold constellations of law and biology in contemporary societies. Drawing on science and technology studies, political theory and legal anthropology, the book attends to the co-production of legal knowledge and biotechnological practices and convincingly shows how they

challenge our understanding of the human and reconfigure concepts of property, personhood, kinship, community and identity.”

—Thomas Lemke, *Professor of Sociology with Focus on Biotechnologies, Nature and Society, Goethe University, Frankfurt, Germany*

“Moving well past existing research that connects the separate regimes of law and the biosciences, this book illuminates their coproduction in the generative field of *biolegalities*. Van Wichelen and de Leeuw offer a significant theoretical advance in defining this compelling new paradigm. Drawing on many exemplars from the latest practical developments, they offer cutting-edge insight into the ecology of tensions and transitions in politics, life, biotechnology and law that continue to unsettle and shape the legalities surrounding human conditions of existence.”

—Margaret Davies, *Matthew Flinders Distinguished Professor, Flinders University, Adelaide, Australia*

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1

Introduction: Biolegality as Critical Intervention

Welcome to a CRISP(e)R World

In 2012, microbiologists Emmanuelle Charpentier and Jennifer Doudna made a discovery that would usher into existence the world of gene editing.¹ They had discovered how an enzyme (Cas9) in combination with CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats)—a bacterial immune system—could cleave to specific parts of DNA, demonstrating this system can be adapted to make targeted cuts in a genome, modifying a DNA sequence. Although still in its early stages, the technique is heralded for its possible future uses in various domains, including all kinds of genomics, disease models, and anti-microbials, as well as agricultural, food, and biotechnological applications (Barrangou and Doudna 2016). As a genome editing tool, CRISPR-Cas9 transformed the scientific community because it is more accurate, efficient, and cheaper than other genome editing techniques.

As labs around the world experiment with gene editing, they are, among other things, editing whole organisms to study disease resistance, changing wheat to more effectively resist pests, altering chromosomes and mutations in mice to tackle cancer and hereditary disease, and editing the DNA of pigs to grow organs for transplantation. But the most

divisive application is that of human germline gene editing; the heritable alteration of germ cells (those that grow into eggs and sperm). As the scientific community advises strict caution, laws and regulations across the world prohibit the use of germline editing for reproduction. Yet, in 2018, the Chinese scientist He Jiankui used the technique to edit human embryos, with the intent, according to He, to eradicate the potential HIV infection for these babies and their offspring.² With this event, the world witnessed the first “CRISPR’d babies” (Greely 2019), a move seen by many as tremendously controversial and having far-reaching consequences.³

Like with all other new biotechnologies (one only needs to think back to the first IVF baby) gene editing is accompanied by thrill as well as fear. The thrill consists of the promise that the science will, for instance, eradicate disease more effectively, or provide better and more nutritious crops to feed the growing world population.⁴ But there is also fear that the technology will bring calamity and disaster to humanity, society, and the environment. The case of He Jiankui prompted wide public discussion whether gene editing in humans will foster new eugenic practices through the creation of “designer babies.” Changes made to the human germline are also heritable, affecting future generations, and raising questions about how gene editing will shape humanity’s future. This technique asks us to consider, how to deliberate and manage the idea of eliminating unwanted traits or enhancing desirable ones? How gene editing, by tinkering and interfering with nature, might enhance biological warfare or extinguish species and ecologies (Andorno et al. 2020; Braverman 2017; Doudna and Steinberg 2017)?

In responding to these fears, society calls upon bioethics, and the legal field calls upon biolaw, to deliberate and bring clarity to the matters at hand. Established in accordance with various national priorities and from an existing pool of experts, bioethical committees provide recommendations that inform institutional guidelines and regulation. The response to He exemplified the centrality of moral and ethical deliberation by experts; rules are to be formed from these deliberations, demarcating boundaries of how far scientists should go in editing human genetic material. The field of biolaw—developed primarily in

continental Europe since the 1990s—complements bioethics by incorporating bioethical principles within the language and institutions of law. Bioethics—as the philosopher Peter Kemp argues—cannot be disentangled from biolaw, for bioethical principles inform how biolaw should be shaped: “bioethics is the ethics of the body, and the ethics of the body is the foundation for biolaw” (see Kemp quoted on p. 215 in Poland 2005).

Our approach to biolegality is not an attempt to replace bioethics or biolaw. Nor is it the constitution of a particular regime of biolaw and bioethics that ultimately shapes how they relate to one another, i.e. the ways that certain bioethical norms are codified in biolaw and the ways applications of biolaw (outcomes) refine bioethical norms through existing practices. Rather, biolegality exists alongside bioethics and biolaw as a useful conceptual device to address how biotechnological advances and practices affect our existing legal institutions, forms, and knowledge, while at the same time, constructing for people, communities, and societies, new or altered forms of relating to biological and biotechnological knowledge. This means that biolegality refers as much to the *outcome* of bioethics and biolaw as to that which *informs* it in the first place. While conventional bioethics and biolaw is vital for the stimulation of public debate and to changing existing, or forming new, regulations and law around biotechnologies, the study of biolegality illuminates two core entanglements of biotechnology and law that the twin concepts of bioethics and biolaw fail to account for: (1) the political dimensions regarding legal governance and (2) the knowledge practices informing legal form.

First, using the case of gene editing we started this introduction with, we can see the ways mainstream bioethics—especially the Anglo-American strand—fails to explain the political dimensions of emerging biotechnologies, in effect depoliticizing the institutional interests underpinning contemporary problems in biology and law, thereby naturalizing the biopolitical (see p. 13 in Swiffen 2010, see also Obasogie and Darnovsky 2018). By naturalizing the biopolitical, we mean the ways in which modern law since the nineteenth century, and Western (US) bioethics since the 1970s, have framed the organization of political life

as conditioned upon certain bodies and populations and their capability to be (socially) healthy, thereby extending the “make live, let die” ethos—onto apparatuses of (neo)liberal governmentality. Indeed, such depoliticization can ironically be understood as a politics of bioethics (Petersen 2011), or more aptly as the bioethical “politics of anti-politics” (Brown 2002). From the very beginning, gene editing evoked a deep worry among the general public about its implications. However, as Sparrow and Mills explain, Anglo-American bioethics “struggles to articulate this unease or indeed to discern much wrong at all with using CRISPR-Cas9 to genetically modify human beings in vitro” (see p. 2 in Sparrow and Mills 2021). There seems to be a gap, then, between what biotechnologies evoke in people’s imagination, and the way in which bioethics can readily engage these thoughts.

The expansive study of biopolitics has successfully addressed this gap.⁵ By studying the political legitimacies behind existing and desired regulatory frameworks and governance systems—themselves often conditioned by power differentials and the interests of states and markets—we can better understand what the stakes are in debates around bioscientific developments like gene editing and how regulatory policies address these stakes. The relationship between law and bio(techno)logy, however, assumes its own dynamic that must be differentiated from the operation of biopolitics. Bioethics and biolaw play a particular role in the constitution of the biopolitical and biolegality is a way of explaining this role, first, by bringing back the political into the ethico-legal appraisals of biotechnology, and second by focusing more explicitly on the material artefacts produced by regulatory institutions in their interactions with bioscientific knowledge (Lezaun 2006). While biopolitics critically examines the normative and ideological dimensions informing policy and governance (including legal instantiations), biolegality offers a lens through which to understand the constitution of biolegal objects more specifically, namely those molecularized or bioengineered normative forms that have the capacity to reorder social life and their institutions (Jasanoff 1997, 2001; Lezaun 2006; Lynch and McNally 2009; Lynch et al. 2010; Pottage 2007).

Second, recent developments in the life sciences focus on the *making* in addition to the *knowing* of nature and biology (Rabinow 1992,

2010), a shift epitomized by the example of gene editing but also of synthetic biology more generally. During the 1990s the focus of the Human Genome Project was to map the sequences of human DNA and the genes of the human genome. The emphasis was on what kind of information this mapping provides and how this information might assist in the development of (agricultural or biomedical) technologies and therapeutics. In contrast, the turn to slicing and editing assumes control over heritability, thereby providing scientists the capacity to change specific traits of any organism. The anthropologist Paul Rabinow observed this turn with the advent of synthetic biology—the bioscientific branch involved in the engineering of organisms—and marked it as the *enculturalization* of nature (1992, 1998, 2010).⁶ Of course, nature in itself is a social and historical construction, but the way in which we have related to nature, particularly in modernity, is as if it is ahistorical, universal, and given (Latour 1999). Rabinow argues that bioscientific developments such as synthetic biology (and we can now include gene editing) are changing the premises of this construction. As Rabinow shows, objections against the “unnaturalness” of GMOs (or artificialness of gene editing) pose a challenge and opportunity, rather than a threat to, or the end of biotechnology; it is not inconceivable that the genetically altered human becomes the desired biology, just as genetically modified tomatoes have become the desired natural tomato.

The shift from knowing to engineering affects the knowledge practices that inform legal form. Bioethics and biolaw struggle to address these changes in knowledge practices. As we describe more fully below, this is because their methodological frameworks—attached to either prescriptive normative and philosophical principles or formal and doctrinal law—cannot account for the legitimating systems or ideas that accompany the changing knowledge practices taking place across institutions, people, communities, and societies in the context of bioengineering. As a conceptual tool working alongside bioethics and biolaw, bioglegality can help examine how bio(techno)logical advancement in the biopolitical age engages, troubles, and rearranges legal form and reorders the construction of biology or nature, and what this reordering generates in the realm of knowledge and sociality.

This approach goes against the common assumption in media and public discourse that law *lags* behind science and technology, and that “catching-up” is what law needs to do to render its instruments compatible with the latest developments—both in terms of efficiency as well as ethics. In our example of gene editing, the “law lag” principle assumes that the practical and ethical questions around gene editing will be settled once law—with the help of bioethics—catches up to regulate the new technology. But bioscientific developments do not occur in a legal vacuum. On the contrary, the production of the gene editing technique itself, as well as the ensuing debates regarding what is permissible, are both conditioned by prevailing legal norms, those concerned for instance with research ethics, intellectual property, and the integrity of human dignity and biological diversity. Courts play a central role in integrating technological developments into society (Jasanoff 1997: 180) and push actors to revisit existing regulations. They evoke public discussion on the question how and to what extent biotechnological advances are to be integrated in our biological, social, and institutional lives. The Science and Technology Studies (STS) scholar Sheila Jasanoff argues in this respect, that instead of the “law lag” principle, law and science more aptly follow the process of “co-production” (2001). Here, epistemic, and normative understandings of life are reordered by law and science in a recursive fashion: one does not follow the other, but are mutually constituted. While the bioethical premise informing a new technique such as CRIPR-Cas9 necessarily assumes the well-rehearsed thesis that “law lags behind science,” the *biolegal* premise points to the coproduction of biology and law. Here, law works from an internal dynamic, though not cut off from other legitimating systems.

To illustrate, following the outrage around He Jiankui’s experiment, the emerging literature on human germline gene editing describes the immense difficulties for institutions grappling with how to set up new rules governing experimentation. The Dutch legal scholar Britta Van Beers, however, rightly emphasizes that within the Euro-American context, legal frameworks around heritable human genome editing already existed since the late 1990s. Based on human rights discourse, these regulations either outright banned human genome editing, as in European countries, Australia, Canada, and Brazil, or allowed some

form of the practice, though chiefly for research purposes, as in the US, the UK and China (Van Beers 2020: 8). The ethical or non-ethical practice of gene editing relies heavily on these already existing regulatory frameworks (governance of biomaterials, regulations around GMOs and LMOs, regulations around reproductive technology and cloning, etc.). Again, the idea that “law lags” scientific or technological accomplishments is inadequate; instead, these accomplishments develop through, against, or because of existing laws. The demand for regulation has, apparently, not been evoked by a lack of regulation, but by a more complex system of biolegal imaginaries and practices, emerging from scientific communities or publics and their desires for, or fears, of engineerable societies.

Gene editing troubles the modern and genetic stability of heredity by introducing a more extreme, more efficient, and more affordable way of altering life than the “genetic modification” of the recent past. The ensuing debate in Euro-American contexts, then, is how to regulate the science and industry that are altering crops and other biological material (including embryos and fetuses) through genome editing. In the case of human germline gene editing, regulatory calls are moving toward regimes of self-regulation by scientific communities. Critical observers see such a move as problematic for several reasons, though most clearly because such regimes exclude social and public participation (Greely 2019; Jasanoff; Hurlbut and Saha 2015; Sparrow and Mills 2021; Van Beers 2020). Epistemologically, gene editing disturbs the stability of knowledge premised on the principle that we cannot change the genetic makeup of biological life. Ontologically, it is remaking life itself. The legal premises through which gene editing occurs and the legalities that ensue through its practices will generate new knowledge as well as new subjectivities and socialities. These social realities need the attention of publics and citizens and bring back the political, thereby refusing the anti-politics of bioethics.

Of course gene editing is just one of the developments in contemporary bioscience that are complicating issues emerging at the intersection of law and biology, just one item in this long but still partial list:

gene drives, genetic privacy, genetically and living modified organisms (GMOs and LMOs), biobanks, transgenic animals, nanotechnology, neuro-interventions, hormonal therapies, cryopreservation, pre-implantation genetic diagnosis (PGD), and mitochondrial replacement techniques. Moreover, these developments will eventually impact a wide-ranging area of law including—though not limited to—administrative, constitutional, contract, corporate, criminal, environmental, family, health, intellectual property, international law, tort, and human rights law. Our aim is not to give an exhaustive account of all these changes. Rather, this book singles out particular “slices of life” or “lively things” (see p. 16 in Winickoff 2015)—of *genes, brains, babies, bodies*, (and *viruses* in the epilogue)—to describe how biotechnology’s reworking of law effects anthropological understandings of exchange, self, kinship, and community.

In the rest of this introduction, we advance our approach to biolegality and argue for its significance in understanding the entanglement of biology and law in contemporary society. We start with a discussion around how biolegality moves away from both conventional bioethical frameworks and scholarship in biolaw based in a doctrinal understanding of legal processes. Biolegality finds its affinity with biopolitical frameworks. However, as we describe the original context in which the term was born, namely in the field of forensics and criminal law, we place the term in a broader historical and empirical context of biology and law. We demonstrate how studies in biolegality can assist us beyond formal legal and ethical inquiries and contribute more forcefully to understanding the antagonistic—though intimate—relationship between the political dimensions of law and the knowledge practices informing legal and cultural forms. In the penultimate section we reflect on the question of temporality and assess whether these shifts in the relationship between law and biology can be designated as “new.” Rather than signaling an epochal shift, we argue that the changes resemble “tipping points” (Tsing 2005) that change how law and life understand their engagement with the social; with the “wholes and the parts” of society (Strathern 1992). We end with a summary of the chapters.