EDITORS' NOTE

This themed edition of the *Macquarie Law Journal* was inspired by a workshop held by Macquarie University in December 2014 on the ethical, legal and social issues raised by synthetic biology research. The 'Ethics and Regulation of Synthetic Biology' workshop stemmed from Macquarie University's involvement in synthetic biology research and its desire to engage in a multi-disciplinary discussion of issues raised by such research. It was organised by Dr Sonia Allan of the Macquarie Law School and Professor Wendy Rogers of the Department of Philosophy, pursuant to a grant jointly received by them from the Faculty of Arts and administered by the Centre for Agency, Values and Ethics at Macquarie University. The university was honoured to have the workshop opened by Professor Mary O'Kane, the NSW Chief Scientist and Engineer, and chaired by Professor Catriona Mackenzie, Fellow of the Australian Academy of the Humanities and an Executive Board Member of the Centre for Agency, Values and Ethics.

This edition, the 15th volume of the *Macquarie Law Journal*, features a collection of very interesting and topical pieces that largely reflect discussions and presentations from that workshop. It differs from many earlier editions of the *Macquarie Law Journal* in that the pieces included are not limited to discussions of the law. Instead, the articles present a range of issues for discussion that are relevant to the ethical, legal and social dimensions of synthetic biology and beyond. All of them have possible implications that will need to be addressed by legislators, regulators and courts. Indeed, the discussion at the workshop, and the articles herein, highlight the fact that consideration of whether to regulate emerging technologies, and if so how, requires contributions from many fields and diverse stakeholders. Included therefore is discussion of perspectives from science, ethics, sociology, law, civil society, and more. It is only by taking a multi-disciplinary approach that issues raised by new technologies can be fully explored, and decisions taken about the best ways to proceed in an area that promises many benefits but also poses some risks. The contributions are ordered to reflect, firstly, the breadth and depth of issues discussed at the workshop and then some wider ranging issues to do with emerging technologies and future challenges.

We start the edition with an informative report by Sonia Allan on the proceedings of the workshop. The report includes an introduction to Macquarie University's involvement in synthetic biology research through the Synthetic Yeast (*Sc2.0)* project, a discussion of the field, and a synopsis of her presentation on the day of the workshop. In particular, it provides a summary of the following: the 'promises and perils' of synthetic biology; a discussion of various international and national regulations relevant to synthetic biology (and possible gaps); and responses to the technology, ranging from cautious support to calls for moratoria. It also provides discussion of 'soft law' regulatory approaches being adopted by some researchers involved in synthetic biology research, and specifically by all those involved in the *Sc2.0* project. The report notes that it should not be read as a stand-alone document. While introducing some of the key regulatory issues, Dr Allan's report highlights the importance of engaging with other disciplines to understand the ethical, legal and social issues raised by synthetic biology. It therefore provides the foundations for the discussion to be found in the subsequent articles and commentaries.

The report is followed by a commentary by Jane Calvert and Emma Frow on the Synthetic Yeast Project. Dr Calvert was the keynote speaker at the Macquarie University workshop. In their article 'The Synthetic Yeast Project as a Topic for Social Scientific Investigation', the authors discuss the *Sc2.0* project (and some of its precursors) in detail, identifying the technical, social and conceptual issues that they find particularly salient as researchers in Science and Technology Studies. They discuss design principles that are central to the project, and identify its preference for open intellectual property. Their article points out that

the project encourages consideration of the spatial and temporal dimensions of organisms, and discusses how the project may assist in exploring tensions between engineering and biology. This paper is an important contribution to the discourse as it provides insight into the project from a social scientist viewpoint. It has regulatory importance because it enables us to reflect upon different aspects of the emerging technology in a way that could not be done without such a perspective.

The short article by Wendy Rogers, titled 'Ethical Issues in Synthetic Biology: A Commentary' raises important considerations about agenda setting, the role of bioethics in synthetic biology, and the subject of 'professionalisation' in the synthetic biology context. Professor Rogers discusses not only the promise of new and exciting technologies such as synthetic biology, but also the challenges in shaping and directing the field to minimise the risk of harm. Hers is an important and insightful piece to consider and leads well into the article written by Ainsley Newson.

Ainsley Newson's contribution, 'Synthetic Biology: Ethics, Exceptionalism and Expectations', highlights that synthetic biology gives rise to ethical implications which, although well recognised in academic and lay literature, are now being given increasing attention from policy makers. Her article then explores the question of whether there is anything singular about such issues that might justify a distinctive or 'exceptional' approach to synthetic biology when compared to other emerging bio-technologies that also raise ethical issues. Her insightful paper argues that the field, while not perhaps warranting a purely exceptional approach, does require engagement with ethics. Dr Newson discusses some under-explored lines of enquiry, and places her discussion within the wider realm of ethical engagement with emerging technologies. Her article is important for considering both ethical engagement with synthetic biology and the insights such engagement may have when contemplating regulation of the field.

A short research note follows, jointly penned by Karolyn White and Subramanyam Vemulpad under the title 'Synthetic Biology and the Responsible Conduct of Research'. In their contribution, the authors contend that synthetic biology poses no special issues in respect of the Australian Code for the Responsible Conduct of Research or for Institutional Biosafety Committees. Their view is that researchers working in the area, as well as regulatory agencies, have been proactive in seeking appropriate governance and considering potential risks. They address, and offer an assessment of, existing regulatory frameworks that provide a structure for safe practices and the mitigation of risks in synthetic biology.

The article by Lisa Eckstein, 'Regulatory Challenges of Synthetic Biology Trials and Other Highly Innovative Investigational Products', discusses possible regulatory challenges for the future and focuses upon issues surrounding clinical trials in humans. In her contribution, Dr Eckstein recognises that while synthetic biology remains in the early stages of innovation, achieving one of its posited goals of improving human health will depend on future clinical trials. She therefore explores Australia's capacity to ensure that clinical trials involving these kinds of highly innovative investigational products have an acceptable initial and ongoing risk-benefit ratio. The author argues that none of the current regulatory bodies in Australia — as they currently operate — are equipped to undertake the necessary reviews that will be required in the future. She therefore canvasses strategies for better supporting them in this role. The article provides important insights into how regulatory approaches may need to be fine-tuned into the future.

We are also grateful to have a further contribution on the subject of synthetic biology by David Mercer, an accomplished academic in the field of Science and Technology who has previously published on the topic of synthetic biology. In his article '"iDentity" and

Governance in Synthetic Biology: Norms and Counter Norms in the "International Genetically Engineered Machine Competition" (iGEM)', Dr Mercer provides a critical evaluation of the ethos of the iGEM competition, which is an annual world-wide student-based synthetic biology competition. He contends that the often stated iGEM goals of collaboration, interdisciplinarity, sharing of results, and overt commitment to the consideration of social and ethical implications of scientific work may be hard to achieve in practice and do not always play out either in the competition or across the emerging field as a whole. To this end, his argument is that policy makers need to move beyond 'symbolically important' parts of the field, such as iGEM, when addressing the challenges of regulation and governance of synthetic biology.

Finally, we have a contribution from one of our own student editors that moves beyond the subject of synthetic biology. The case note by Valiant Warzecha reminds us that emerging bio-technologies pose regulatory challenges in many senses, and it explores this issue with an analysis of the recent Full Federal Court decision in *D'Arcy v Myriad Genetics*.

We wish to thank all the contributors for their submissions to this edition of the *Macquarie Law Journal* and their cooperation with the editorial staff during the production phase. Of course, particular thanks must also go to the hard working and enthusiastic student editors, students of Macquarie Law School, whose commitment and perseverance made the publication of Volume 15 possible.

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