Synthetic Biology – An Opportunity for Soft Law Governance 2.0

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Synthetic biology is the latest emerging technology on a collision course with our traditional government regulatory paradigm. Such technologies have distinct characteristics that confound conventional regulation – including a rapid pace of development and change, unusually large uncertainties about future applications, benefits and risks, a diverse range of industries and users who will apply the technology in very different ways, and a broad set of potential risks and concerns that include but go beyond traditional regulatory triggers of environmental and health risks to also include bioethical, socio-economic, privacy and equity issues. While traditional government regulatory will play an important role in the oversight of synthetic biology, government regulation will likely be inadequate and too slow to provide satisfactory governance of synthetic biology.

"Soft law" governance approaches can supplement traditional government regulation. "Soft law" consists of private standards, guidelines, codes of conduct, principles, certification programs, voluntary programs, and partnership programs that establish substantive requirements that are not directly enforceable by government. Governmental agencies may play an important role in some soft law programs, but private companies, trade associations, non-governmental organizations, think tanks, standard-setting organizations and certification bodies may also play important roles. Soft law programs have several potential inherent advantages – they can be established and revised more quickly than government regulation, they often involve cooperative rather than adversarial relationships, and they extend across traditional legal jurisdictions and so can apply internationally. But soft law programs also have their problems, including limitations on public participation and transparency, incomplete participation and coverage, and inadequate enforcement and compliance.

Nanotechnology was the predicate test case for the soft law governance of synthetic biology. While soft law approaches have been applied to a wide variety of technologies and regulatory problems, nanotechnology represented the first major technology where soft law approaches played a dominant role. While regulatory agencies in the United States, European Union and elsewhere struggled to slowly define, characterize, evaluate and regulate nanomaterials, a wide variety of nanotechnology soft law programs were developed to try to fill the regulatory void. These soft law programs included nanotechnology risk management standards by international standard-setting organizations (e.g., ISO), government voluntary programs (e.g., EPA's Nanoscale Materials Stewardship Program), industry-NGO risk management programs (e.g., EDF-DuPont NanoRisk Framework), codes of conduct (e.g., E.U. Code of Conduct for Responsible Nanosciences and Nanotechnologies Research), inter-governmental coordination networks (e.g., OECD Working Party on Manufactured Nanomaterials), industry consortiums for joint testing and research (e.g., NanoSafety Consortium for Carbon), and certification programs (e.g., CENARIOS). The effectiveness of these nanotechnology soft law programs was mixed, with some providing modest benefits while others were less successful.[1]

Nonetheless, the experience with nanotechnology soft law programs can provide important lessons for synthetic biology. These lessons include the need for objective measures of accountability and enforcement,[2] the importance of regulatory "backstops" to induce participation and compliance,[3] and

the potential leverage provided by insurance providers and liability avoidance to encourage participation in soft law programs.[4]

Soft law governance mechanisms are likely to play an even greater role in synthetic biology oversight given the inadequacies of existing regulatory programs to govern this diverse technology. There have already been a series of significant soft law applications in the synthetic biology space, including:

National Institute of Health Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) are being adapted and revised for synthetic biology.

- The Synthetic Biology Project created by the Woodrow Wilson Center has launched a web-based Synthetic Biology Scorecard intended to follow and summarize both federal and non-federal efforts to enhance synthetic biology research and development governance, to minimize risk and maximize potential social and economic benefits.

- The Department of Health and Human Services released a Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA to minimize the risk of malicious misuse of synthetic nucleic acid technology.

- The National Science Advisory Board for Biosecurity (NSABB) has produced guidance documents and frameworks for the safe handling of dual use research.

- The International Association for Synthetic Biology, an association of genetic synthesis companies, has produced a Code of Conduct for Best Practices in Gene Synthesis.

- The Do-It-Yourself (DIY) segment of synthetic biology operates outside most formal research and environmental regulations, and has accordingly been the subject of innovative soft law programs such as voluntary guidelines, outreach and network building efforts, and educational programs.

Through these initiatives, soft law may have already played a more significant role for synthetic biology than any previous technology, but this is just the start, and proposals for new soft law initiatives abound.[5] Much work and creativity is needed to make these soft law initiatives succeed – the outcome will play a major role in determining the future and viability of both synthetic biology and soft law approaches.

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[1] Kenneth W. Abbott et al., *Soft Law Oversight Mechanisms for Nanotechnology*, 52 JURIMETRICS 279 (2012).
[2] Diana M. Bowman & Graeme A. Hodge, *Counting on Codes: An Examination of Transnational Codes as a Regulatory Governance Mechanism for Nanotechnologies*, 3 REGULATION & GOVERNANCE 145 (2009).
[3] Daniel J. Fiorino, Project on Emerging Nanotechnologies, Voluntary Initiatives, Regulation, and Nanotechnology Oversight: Charting A Path (2010), available at http://www.nanotechproject.org/process/assets/files/8347/pen-19.pdf.
[4] Gary E. Marchant, '*Soft Law" Mechanisms for Nanotechnology: Liability and Insurance Drivers*, 17 J. RISK RESEARCH 709 (2014).
[5] *See, e.g.,* Gregory N. Mandel & Gary E. Marchant*, The Living Regulatory Challenges of Synthetic Biology,* 100 IOWA L. REV. 101 (2014).