SOFT LAW GOVERNANCE: A HISTORICAL PERSPECTIVE FROM LIFE-SCIENCE TECHNOLOGIES

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ABSTRACT: This Article considers and assesses soft law oversight measures reflected in four historical life science models: (1) recombinant DNA (rDNA) guidelines; (2) gene synthesis self-regulatory programs; (3) professional guidelines for stem cell researchers; and (4) UNESCO declarations. The purpose of the following analysis is to ascertain how certain soft law structures have fared governance-wise with the aim of applying them in the future, in whole or in part, to frameworks not necessarily limited to life science. The life-science examples discussed in this Article are limited to four, but these illustrations are by no means exclusive. In conclusion, this examination will provide suggestions for the successful application of soft law governance based on the lessons learned from the oversight measures applied to the highlighted life-science models.

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Areas of life science have been governed by various methods for decades. Sometimes mother nature resolves an issue manifesting in her habitat. At other times, man must step in. Life science, as the term indicates, consists of a field encompassing all living organisms such as humans, animals, and plants. However, the ways in which each organism is managed or governed may differ depending on the entity in question, its composition, and interaction with the environment as an interrelated whole.

Generally, with respect to governance evaluations, one often makes comparisons to tested methods of management in related, or unrelated, areas to best determine how something novel should be guided or controlled. This is done for efficiency purposes—and if it works, why reinvent the wheel?

There are several life-science governance mechanisms—public and private. These include binding laws, regulations, policies, guidances, best practices, industry standards, and others. Thus, within the scope of life-science management tools there is a spectrum: from those that are legally prescribed and enforced with penalties, to those not directly enforceable by government (though governments may support them, look to them for guidance or establish similar mechanisms themselves).[1] The former is an example of "hard law," the latter is what

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1. Gary E. Marchant, *"Soft Law" Governance Of Artificial Intelligence*, AI PULSE (Jan. 15, 2019), https://aipulse.org/soft-law-governance-of-artificial-intelligence/ [https://perma.cc/5SN9-KJB4].

has become known as "soft law."[2] The oversight body in each case will vary from government to expert groups leading the charge for reliable administration over the matter under scrutiny. The key is zeroing in on the appropriate oversight system to ensure efficacy on the one hand and accord between the scientific community and the general public on the other.

I. RECOMBINANT DNA (rDNA) GUIDELINES

For scientists who have spent years pursuing research, one of the most debilitating things that can happen, should it affect what they are passionately working on, is a moratorium on such experiments. Yet, that is exactly what happened in 1974, when a group of prominent scientific experts called for a voluntary moratorium on a class of experiments involving rDNA (i.e., artificially combining genetic material from different organisms to create a living organism not otherwise naturally found in the environment). The impetus for the moratorium was that some scientists feared, or at least were uncertain about, the potential consequences of the resultant genetic combinations—particularly if they escaped from the laboratory into the ecosystem.

Getting scientists worldwide to agree to the moratorium on certain types of experiments proved to be less difficult than some expected. Perhaps, the swift formation of a committee charged with studying the repercussions of rDNA experimentation and designing effective solutions for any materializing risks likely aided this consensus. The committee, formed by the National Academy of Sciences (NAS), led to the establishment of the Asilomar Conference on rDNA Molecules held in 1975.[3] The ultimate findings of the NAS committee and Asilomar Conference were that rDNA experimentation should and could continue, but only under the direction of specific guidelines (Asilomar Guidelines) thereafter adopted by the National Institutes of Health (NIH).[4] The Asilomar Guidelines, as drafted, were malleable in that restrictions could be lifted or revised as new information on the nature of rDNA experimentation unfolded.[5]

On a related point, there is the issue of novelty to consider. The Asilomar Conference was initiated soon after methods were discovered that eased the production of rDNA.[6] At the time of the Asilomar Conference, rDNA experimentation was much easier to contain and control through measures like a voluntary moratorium, followed by the establishment of practice guidelines—which were deemed highly useful.[7] Almost forty-five years later, the Asilomar (now NIH) Guidelines carry very few restrictions because of the gradually established safety of rDNA research. These Guidelines became famous for their success in

2. *Id.*

3. KATJA GRACE, MACH. INTEL. RSCH. INST., THE ASILOMAR CONFERENCE: A CASE STUDY IN RISK MITIGATION 4 (2015), https://intelligence.org/files/TheAsilomarConference.pdf [https://perma.cc/CJU3-FCXB].].

4. *Id.*

5. *Id. See generally* DONALD S. FREDRICKSON, THE RECOMBINANT DNA CONTROVERSY: A MEMOIR (2001).

6. GRACE, *supra* note 3, at 4.

7. *Id.*

managing perceived risks with voluntary precaution without the need for binding legislation.

There are many similarities and differences between rDNA and other systems ripe for regulation. Many of the basic similarities and differences noted in the immediately following discussion apply to all four examples outlined at the outset and under consideration in this Article (under headings for Parts I through IV), as a way of highlighting the importance of making comparisons when taking soft law management measures into account from an application standpoint.

When it comes to similarities, for the most part, the value and practicality of many new technologies are usually undisputed. However, both rDNA and other biological or mechanical parts, at different points in time, were, are, and will be perceived to carry potential accidental or purposeful human, animal, and ecological risks that should be regulated.

In terms of differences, rDNA involves a live biological and reproducing system, whereas not all systems contain such properties. For example, an entity can be said to impact a live organism while it is not in and of itself a living thing. In addition, it appears that with the breadth of some applications, there are many more risks and benefits to address than those arising from the production of rDNA, potentially requiring a more hard-lined oversight approach. Therefore, in each case, one must consider and compare the potential risk, purpose, scope, maturity of the sector, closeness to market, compliance incentives, and so forth when proposing to implement a soft law oversight measure such as the Asilomar Guidelines.

Furthermore, we now live in the age of digital connectivity. Potential willful misuse of a substance by individuals without beneficial intentions has permeated the fabric of society. As a result, more current soft law guidelines might well have to take greater and even more remote risks into account. The Asilomar Conference focused primarily on imminent rather than on future or more remote risks, as the former were deemed more pressing.[8] Other areas considering Asilomar-type oversight may have to, again, reflect on future "what-ifs" as concrete possibilities.[9] Certain topics, such as biowarfare, were purposely not considered at the Asilomar Conference. When looking to soft law guidelines as favorable guidance mechanisms one must, if their consideration is to be properly executed, "look at what was looked at." Only then can one justifiably claim that a similar path should be taken in a particular instance.

One of the main considerations, when evaluating past oversight programs in the hopes of applying them to other technologies, is their effectiveness *in hindsight*. Regarding the Asilomar Conference, one author notes that "[h]ad the dangers been real, it is hard to know whether the precautions would have substantially reduced the risk."[10] However, that same writer likewise concedes that

8. *Id.* at 11.

9. *See, e.g.*, STUART RUSSELL, HUMAN COMPATIBLE: ARTIFICIAL INTELLIGENCE AND THE PROBLEM OF CONTROL xi (Paul Slovak & Laura Stickney eds., 2019).

10. GRACE, *supra* note 3, at 16.

the Asilomar procedures likely would have been beneficial had real danger (i.e., a higher level of certainty) presented itself.[11]

Nonetheless, when it comes to oversight and taking all of the above into account, experts in their area of competency no doubt prefer to self-regulate. They are arguably more adept, especially resource and experience-wise, to assess present circumstances and future possibilities when it comes to current matters facing oversight— especially given the speed of change and urgency in some cases.[12] Nonregulatory oversight measures should set out to be realistic in the present, anticipatory regarding the future, and adjustable as new information comes to light. They might also consider ethical, legal, and deeper environmental concerns—an oft-cited failure of the Asilomar Guidelines.[13]

The Asilomar Guidelines were, as already noted, crafted in a malleable fashion and served a purpose at the time and anticipatorily for the future. Experts assessed the risks and benefits in a transparent forum that kept the public informed (and perhaps some bias at bay)[14] and produced a set of Guidelines deemed acceptable by the government for control and oversight.

Since then, such efforts have led to a

> "commitment at the highest levels to giving citizens more of a voice in the decisions that affect their lives, and to engaging citizens in making government more responsive and accountable" (Cornwall, 2008, p. 11). In a 2000 report, the U.K. House of Lords recommended that dialogue with the public be a mandatory and integral part of policy processes, including the use of public meetings as a tool for formal citizen engagement (U.K. House of Lords, 2000). Likewise, the 2003 U.S. Nanotechnology Research and Development Act mandated "convening of regular and ongoing public discussions, through mechanisms such as citizens' panels, consensus conferences, and educational events."[15]

This is an issue that has been said to have affected the genetically modified organism (GMO) industry in that "a lack of meaningful engagement with different publics when [GMOs] were first introduced did irreparable damage to the emerging scientific field of genetic engineering."[16]

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11. *Id.*

12. For example, consider the COVID-19 pandemic responses. *See, e.g.*, Barbara J. Evans & Ellen Wright Clayton, *Deadly Delay: The FDA's Role in America's Covid-Testing Debacle*, 130 Yale L.J. Forum 78, 92 (2020) (discussing the harmful impact of oversight on COVID-19 testing).

13. Paul Berg & Maxine F. Singer, *The Recombinant DNA Controversy: Twenty Years Later*, 92 PROC. NAT'L ACAD. SCI. U.S. 9011, 9012 (1995).

14. Paul Berg, *Asilomar 1975: DNA Modification Secured*, 455 NATURE 290, 290 (2008) ("[T]he public seemed comforted by the fact that the freeze had been proposed by the very people who had helped develop the technology.").

15. COMM. ON HUM. GENE EDITING: SCI., MED., & ETHICAL CONSIDERATIONS, NAT'L ACADS. OF SCIS., ENG'G, & MED., HUMAN GENOME EDITING: SCIENCE, ETHICS, AND GOVERNANCE 163–64 (2017), https://www.nap.edu/catalog/24623/human-genome-editing-science-ethics-and-governance [perma.cc/XF85-8W5T] (follow "Download Free PDF" hyperlink).

16. *Id.* at 164.

When it comes to practicality, the Asilomar Guidelines' ultimate effectiveness is difficult to assess given the technology's safety record over the years, which by many is alleged to be the result of overstated potential dangers:

> Some scientists and public officials as well, were certain that recombinant DNA research was flirting with disaster and that lifting the moratorium was a blunder. Others, reflecting their intuition and expertise, argued that such cells, viruses and recombinant DNAs posed no risk at all. The overwhelming assessment today is that the latter view was correct. Literally millions of experiments, many even inconceivable in 1975, have been carried out in the last 20 years without incident.[17]

When it came to the effectiveness of *following* the Asilomar Guidelines, this was not an issue given that adherence was tied to receiving NIH funding. This is an important factor to highlight because NIH funding is often the bread and butter of scientific research and progress. For instance, receiving external grants is high on the list of financial expectations of institutions of higher learning, who then also benefit from funded research (through recognition and cost savings).[18] Perhaps one of the most notable aspects of the Asilomar Guidelines is that although they were only mandatory for NIH-funded research, the private sector generally complied with them voluntarily, likely to avoid or mitigate liability.

II. GENE SYNTHESIS SELF-REGULATORY PROGRAMS

Gene synthesis involves laboratory methods of creating DNA sequences for various beneficial applications in synthetic biology. It can also serve a dual use in the production of infectious and deadly organisms—referred to as bioweapons. For this reason, the synthetic gene industry recognized the necessity for oversight when, for instance, a company sells such genes and must be aware of what sequences could result in the malevolent application of the technology. In this arena, there has been a push for voluntary behavioral codes of conduct that, above all, are transparent[19] and involve consideration of certain levels of ethics training[20] for scientists working in the field of synthetic biology and, specifically, gene synthesis.[21]

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17. Berg & Singer, *supra* note 13, at 9011.

18. *See* Jason Alvarez, *UCSF Remains Top Public Recipient of NIH Funding for 13th Straight Year*, U.C. S.F. (Apr. 1, 2020), https://www.ucsf.edu/news/2020/04/417061/ucsf-remains-top-public-recipient-nih-funding-13th-straight-year [https://perma.cc/KZT3-3394].

19. Stephen M. Maurer, *Taking Self-Governance Seriously: Synthetic Biology's Last, Best Chance to Improve Security* 11 (U.C. Berkeley Goldman Sch. of Pub. Pol'y Working Paper, Paper No. GSPP12-003, 2012), https://ssrn.com/abstract=2183306.

20. In science, specifically with regard to biological weapons, codes of ethics have been developed by entities such as the American Society for Microbiology, U.S. Council for Responsible Genetics, the International Network of Engineers and Scientists for Global Responsibility, and others. Brian Rappert, *Codes of Conduct and Biological Weapons: An In-Process Assessment*, 5 BIOSECURITY & BIOTERRORISM: BIODEFENSE STRATEGY, PRAC., & SCI. 145, 147 (2007).

21. R.E. Burnett, Deterring Bioweapons (Guilleman MIT 2007): The 2009 Case of The International Gene Synthesis Consortium—Codes of Conduct and Science Worker Ethical

When it comes to gene synthesis, there was great consensus within the industry to establish standards that would apply widely for biosecurity purposes. The International Gene Consortium (IGSC), established in 2009 to enable gene synthesis applications while at the same time tempering conceivable abuse (along with its Harmonized Screening Protocol updated in 2018), is one example of an accepted coordinated screening and restraint protocol adopted by 80 percent of entities operating in the gene synthesis space.[22] This system creates a "black list" of dangerous DNA sequences that, if obtained by the "wrong" hands, could potentially create a global health crisis. Although the IGSC program has generally been successful in helping to keep pathogenic DNA sequences out of the hands of prospective bioterrorists, the program has been criticized for being lax when it comes to actual implementation in certain areas such as reporting concerns and vetting new customers. However, no system is perfect[23] whether self-governed, legislated, or a combination of both. Entities who initially fail or refuse to adopt a common set of private guidelines must have some skin in the game (e.g., market force pressure; being subject to potential liability) to eventually push them to join the majority that has accepted industry-developed protocols.

Nevertheless, one of the lessons from IGSC is that industry-wide voluntary programs are unlikely to garner 100 percent participation, and so the question is whether getting a majority of industry members to participate is still useful and effective. This is arguably best answered by Maurer and von Engelhardt, "[s]elf governance displaces the chaos and, one can hope, empowers reasonable people,"[24] thereby eventually converting initial nonparticipants to accept and follow voluntary governance programs.

Self-regulation has been recognized by leading scientific organizations such as the National Science Foundation, NAS, the American Association for the Advancement of Science, and other institutions as a way to control industries like synthetic biology. Producing a set of industry standards of conduct can be more effective in terms of (1) time (compared to enacting legislation); (2) effectiveness (industry likely having a more thorough understanding of its product and its detrimental repercussions); and (3) promoting innovation in an increasingly competitive and less regulated global environment.[25] Indeed, it has been noted that "self-governance can be significantly *more* stringent than formal regulations."[26] However, one could argue that for such a system to be highly effective it needs to be valued by its adherents and place few limits on innovation and progress, while appropriately restraining current and future catastrophes.

Knowledge, Annual Meeting of the Am. Pol. Sci. Ass'n 16 (Sept. 2–5, 2010) (unpublished manuscript), https://ssrn.com/abstract=1644629.

22. *About IGSC*, INT'L GENE SYNTHESIS CONSORTIUM, https://genesynthesisconsortium.org/ [https://perma.cc/QYJ6-6GMN].

23. *See* Maurer, *supra* note 19, at 10.

24. Stephen M. Maurer & Sebastian von Engelhardt, *Industry Self-Governance: A New Way to Manage Dangerous Technologies*, 69 BULL. ATOMIC SCIENTISTS, May 2013, at 53, 59.

25. *Id.* at 59–60.

26. Maurer, *supra* note 19, at 9.

III. STEM CELLS

On May 12, 2016, the largest global stem cell research professional association, the International Society for Stem Cell Research (ISSCR), released its revised guidelines pertaining to stem cell research and accompanying medical applications.[27] A couple of the main themes that run throughout the ISSCR guidelines are the concepts of ethics and transparency.[28]

The focus on ethics and morality in emerging technologies is not new. Many esteemed and credible associations, groups, and committees spend countless hours considering ethical issues together with technological advancements. However, despite laudable efforts, individual scientists have been known to stray from ethical standards, which directly affects transparency and public trust. Enhanced security through ethical training is only as effective as the scientists behind the system. However, this issue may be resolved with the institution of properly funded oversight bodies[29] created to monitor industry activity and adherence to professional codes and procedures—similar to Institutional Review Boards (IRB) in human subject research.

So long as the rules are effective, scientists (or other relevant groups) would likely prefer to abide by internal or soft law codes of conduct than cumbersome, legally restrictive regulations. This is where adherence to ethical principles and morality within the context of soft law has its strongest foothold: be cautious and verify red flags thoroughly or risk potentially heavy-handed government interference.

A key aspect of the ISSCR guidelines is that they are international in application. Because they are promulgated by an international scientific society with members across the world, these international guidelines are not limited to specific legal jurisdictions like traditional regulation. In terms of benefits,

> [i]nternational standards bodies have a track record of governing a range of socio-technical issues: they have spread cybersecurity practices to nearly 160 countries, they have seen firms around the world incur significant costs in order to improve their environmental sustainability, and they have developed safety standards used in numerous industries including autonomous vehicles and nuclear energy. These bodies have the institutional capacity to achieve expert

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27. Press Release, Int'l Soc'y for Stem Cell Research (ISSCR), ISSCR Releases Updated Guidelines for Stem Cell Research and Clinical Translation (May 12, 2016), https://www.isscr.org/news-publicationsss/isscr-news-articles/article-listing/2016/05/12/isscr-releases-updated-guidelines-for-stem-cell-research-and-clinical-translation [https://perma.cc/5DH6-25SA]. *See generally* INT'L SOC'Y FOR STEM CELL RESEARCH, GUIDELINES FOR STEM CELL RESEARCH AND CLINICAL TRANSLATION (May 2016), https://www.isscr.org/docs/default-source/all-isscr-guidelines/guidelines-2016/isscr-guidelines-for-stem-cell-research-and-clinical-translationd67119731dff6ddbb37cff0000940c19.pdf?sfvrsn=4.

28. Jonathan Kimmelman et al., *New ISSCR Guidelines: Clinical Translation of Stem Cell Research*, 387 LANCET 1979, 1979 (2016); Jonathan Kimmelman et al., *Global Standards for Stem-Cell Research*, 533 NATURE 311, 313 (2016) [hereinafter Kimmelman et al., *Global Standards*]; George Q. Daley et al., *Setting Global Standards for Stem Cell Research and Clinical Translation: The 2016 ISSCR Guidelines*, 6 STEM CELL REPS. 787, 788 (2016).

29. Amy E. Smithson, *Pathogens and Arms Control: Can Bioscience Police Itself?*, 52 SURVIVAL 117, 120 (2010).

> consensus and then promulgate standards across the world. Other existing institutions can then enforce these nominally voluntary standards through both defacto and dejure methods.[30]

Another important aspect of the ISSCR guidelines is that the *Nature* family of journals announced it will only publish articles in the stem cell field that demonstrate compliance with the ISSCR guidelines.[31] This reflects a novel mechanism for indirectly enforcing soft law provisions such as professional society guidelines. *Nature's* new standard had an impact because *Nature* journals are some of the most prestigious journals in the world that scientists from every country covet for publication purposes.

It has been pointed out that voluntary guidelines without recognized and established players supporting them may lack the bench strength required for effectiveness.[32] Nonetheless, while certain individuals believe that government should be regulating and overseeing emerging technologies (especially in areas involving safety, efficacy, and ethics), the pace of enacting legally binding documents is such that by the time enactments and effective dates are established, technology has already moved beyond what once was its initial issues and concerns. As expressed by Jonathan Kimmelman, "International guidelines are better positioned than national laws to help ensure protection."[33]

One of the things that makes emerging technologies unique, whether considering stem cells or other areas, is that their application generally has no borders. Therefore, any governance method should seek to advance or incorporate international implementation and global acceptance and consistency. As already noted, legal measures can take years to craft and apply only to a single legal jurisdiction. In contrast, industry or professional organizations are more apt to have the requisite knowledge and motivation to self or coregulate on a more global and timelier basis. This is the case whether driven by market forces, public confidence, research advancement, or a myriad of other reasons.

IV. UNESCO

The United Nations Educational, Scientific and Cultural Organization (UNESCO)—a branch of the United Nations specializing in the promotion of global collaboration in education, sciences, and human culture—has developed three key declarations relating specifically to genetics and related bioethics. These instruments are not legally binding but have served to guide the international community with regard to the various aspects of genetic and healthcare processes. In order of release, these are the Universal Declaration on the Human

30. PETER CIHON, STANDARDS FOR AI GOVERNANCE: INTERNATIONAL STANDARDS TO ENABLE GLOBAL COORDINATION IN AI RESEARCH & DEVELOPMENT 2 (Apr. 2019), https://www.fhi.ox.ac.uk/wp-content/uploads/Standards_-FHI-Technical-Report.pdf [https://perma.cc/FK84-3WQV].

31. *See Human Embryo and Stem-Cell Research*, 557 NATURE 6, 6 (2018).

32. *See* Tsung-Ling Lee et al., *Regulating the Stem Cell Industry: Needs and Responsibilities*, 95 BULL. WORLD HEALTH ORG. 663, 663–64 (2017).

33. Kimmelman et al., *Global Standards*, *supra* note 28, at 311.

Genome and Human Rights in 1997, the International Declaration on Human Genetic Data in 2003 (IDHGD), and the Universal Declaration on Bioethics and Human Rights in 2005.[34]

The UNESCO declarations emphasize the importance of considering the principles enshrined therein by member States with respect to State policies, regulations, laws, or other documents developed as guidelines or legally binding instruments by such member States.[35] They can also be useful to nonstate actors, such as institutions and individuals in determining their actions and advocating for state policies.

Again, when considering the "enforceability" of the UNESCO declarations themselves, "the question is: Are there many other global intergovernmental organisations that could claim the same level of experience at the intersection of sciences, ethics and human rights? The answer, at least at this stage, seems to be 'no.'"[36] Further, the 2003 IDHGD, in particular, bolstered UNESCO's position in establishing international standards in the area of genetics and bioethical considerations, and permitted member States to establish faith in the organization's capabilities.[37]

These views underscore what has already been noted in this essay, namely, that nonbinding instruments do have teeth. They are useful in and of themselves but also to guide and drive governments to defer to their expertise or incorporate the principles into legally binding rules, if and when deemed necessary. For instance, it has been said that "[t]hese Declarations establish principles that need to be developed and enforced by the domestic laws of the member states."[38] While this may be the case for some governments, for others, guidelines or declarations may be sufficient when it comes to following protocols. With regard to the force of the UNESCO declarations in particular,

> [w]hilst these instruments have no binding legal force, either internationally or under domestic law, they represent important international norms and provide grounds for individuals to challenge laws that run counter to these instruments.

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34. *UNESCO Declarations on Bioethics and Human Rights*, CTR. FOR GENETICS & SOC'Y, https://www.geneticsandsociety.org/internal-content/unesco-declarations-bioethics-and-human-rights#:~:text=The%20Universal%20Declaration%20on%20the,UN%20General%20Assembly%20in%201998.&text=The%20Universal%20Declaration%20on%20Bioethics,after%20two%20years%20of%20development [https://perma.cc/SX6T-BHJY].

35. Herman Nys, Editorial, *Towards an International Treaty on Human Rights and Biomedicine? Some Reflections Inspired by UNESCO's Universal Declaration on Bioethics and Human Rights*, 13 EUR. J. HEALTH L. 5, 6–8 (2006). UNESCO has 193 members and 11 associate members as of 2019. *Member States*, UNESCO, https://en.unesco.org/countries/member-states [https://perma.cc/T4N8-Q5S6].

36. R. Andorno, *Global Bioethics at UNESCO: In Defence of the Universal Declaration on Bioethics and Human Rights*, 33 J. MED. ETHICS 150, 152 (2007).

37. Henk ten Have, *The Activities of UNESCO in the Area of Ethics*, 16 KENNEDY INST. ETHICS J. 333, 340 (2006).

38. Pilar Nicolás, *Ethical and Juridical Issues of Genetic Testing: A Review of the International Regulation*, 69 CRITICAL REVS. IN ONCOLOGY/HEMATOLOGY 98, 99 (2009).

> *Indeed, there is a growing tendency for courts to look at declarations in international law as a guideline*.[39]

Moreover, in terms of the UNESCO declarations,

> It is important to note that if the binding effect were totally absent from them, they would not be "law" at all, because one of the classical distinctions between "ethics" and "law" is precisely that law is made up of *enforceable* norms while ethics is *not enforceable*. Thus, it is misleading to affirm that soft law only creates *moral or political* commitment for States. This is only true if we consider the *immediate* effect of soft law instruments. But the fact is that, in a more indirect and persuasive way, they have an influence on States which is not very different from that of treaties. Indeed, some studies show that, surprisingly, declarations and treaties are complied with to largely the same extent. We should not forget that, after all, soft law instruments are formal intergovernmental agreements, and in this respect they do not differ essentially from the traditional international binding instruments.
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> Furthermore, there is no doubt that the UNESCO declarations have been adopted with the *intention* that in the long run, in one way or another, they will become binding rules for States.[40]

While some commentators have highlighted some of UNESCO's declarations' shortcomings in terms of lack of enforceability and non-specificity,[41] these Declarations have nonetheless played an important role in the global development of the ethics and governance of genetics and associated biosciences.

The lessons learned from the four life-science examples showcased within the context of soft law are as follows:

- Soft law can be an effective governance tool in many areas, and life-science examples may provide a springboard for other disciplines.
- When something requires governance, the swift formation of a committee of experts from various fields is encouraged to assess a course of action.
- Transparency and public involvement in discourse are paramount as a means to better unite the scientific community and general population.
- Society expects the consideration and inclusion of ethical components in governance instruments.
- Malleability in governance, especially with respect to science and technology, is crucial given the speed of change and progress.
- Risks should be assessed from a global perspective.

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39. Margaret Otlowski, *Key Themes in the Policy Debate on Human Genetic Research and Genetic Databanks: An Evaluation*, 5 J. INT'L BIOTECHNOLOGY L. 143, 143 (2008) (emphasis added).

40. ROBERTO ANDORNO, PRINCIPLES OF INTERNATIONAL BIOLAW. SEEKING COMMON GROUND AT THE INTERSECTION OF BIOETHICS AND HUMAN RIGHTS 59 (2013) (ebook).

41. *See, e.g.,* Henriette D.C. Roscam Abbing, *Selected Legislation and Jurisprudence: UNESCO International Declaration on Human Genetic Data*, 11 EUR. J. HEALTH L. 93, 93 (2004); Allyn L. Taylor, *Globalization and Biotechnology: UNESCO and an International Strategy to Advance Human Rights and Public Health*, 25 AM. J. L. & MED. 479, 480, 505–06, 510 (1999).

- Soft law models come in many shapes and sizes. Comparison shopping is good practice.
- Tying soft law approaches to benefits or incentives may very likely encourage participation.
- "Oversight of the oversight" may be necessary (e.g., IRB) to ensure soft law measures are consistently followed.
- Soft law measures must be valued and respected to be observed.
- Continuing education should be required in connection with the principles enshrined in the soft law rules.
- Global application, whenever possible, is encouraged.

Life-science soft law frameworks have been in operation for decades with positive results. These soft law frameworks potentially provide useful models and lessons for future applications. As reiterated often enough herein and as the UNESCO International Bioethics Committee itself stated (in connection with its 1997 declaration): "An instrument not requiring ratification, accession or acceptance, is likely to be adopted more quickly than a formal agreement, whereas the binding nature of a convention could well discourage certain States from committing themselves in so complex and changeable an area."[42]

Many regulatable advancements are moving forward at breakneck speed. Soft law oversight provides humanity with the opportunity to productively keep up with the pace of change.

42. ADÈLE LANGLOIS, NEGOTIATING BIOETHICS: THE GOVERNANCE OF UNESCO'S BIOETHICS PROGRAMME 65 (2013), https://www.ncbi.nlm.nih.gov/books/NBK189523/pdf/Bookshelf_NBK189523.pdf [https://perma.cc/GPU4-G4L7] (quoting Héctor Gros Espiell, *Mechanism for Monitoring the Future Universal Declaration on the Human Genome and Human Rights*, *in* UNITED NATIONS EDUC., SCI. & CULTURAL ORG., BIRTH OF THE UNIVERSAL DECLARATION ON THE HUMAN GENOME AND HUMAN RIGHTS 79, 79 (1999)).