

## 21<sup>st</sup> Century BioLaw: a proposal

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**ABSTRACT:** Providing legal rules for life sciences is not an easy task. On the one hand, for instance, scientific results change rapidly and new areas for research are continuously emerging. On the other hand, legislative procedures are time-consuming and the law risks to be always late. Scientific complexity and ethical divisiveness are also uneasy to deal with by political bodies and courts, requiring precise and specific expertise. In the light of the tricky relationship between life sciences and the law, the article recommends three features that are supposed to help the law in efficiently cope with contemporary and future scientific challenges: openness, updateness, attentiveness.

**KEYWORDS:** Biolaw; Law and life sciences; Health law; Medical law; Anthropocene

**SUMMARY:** 1. Introduction: three challenges for 21st Century biolaw – 2. Anthropocene: Pros and Cons of Life Sciences and Biotechnology – 3. The match between law and life sciences – 4. An open biolaw – 5. An updated biolaw – 6. An attentive biolaw – 7. Threats and opportunities.

### 1. Introduction<sup>1</sup>

Life sciences have always been a strain on legal systems and their categories. Namely, the objective difficulty in understanding very complex scientific vocabularies and notions is joined by the equally (or, perhaps, even more) difficult problem of finding a consensus on very sensitive and divisive issues, where deep moral, ethical and political dilemmas surface.

Three major challenges for the regulation of life sciences can be thus identified.

A first risk on the part of the law is to stay silent or still, paralyzed by both scientific unfamiliarity and ethical disorientation.

Secondly, the rapid pace in the progression of life sciences challenges one of the most significant intrinsic features of the law: the principle of certainty. While uncertainty and the modifiability of their results are normal currency in life sciences, these features are especially problematic in law and they jeopardize the very essence of equality and non-discrimination.

Thirdly, it is worth mentioning that life sciences work on a very diverse set of materials and cases that usually differ from each other. Any even minimum specific traits of the bio-objects must be considered so as to avoid an undifferentiated and therefore unreasonable legal regulation. Law as a codified set of general principles also suffers from this perspective.

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Taking into consideration this problematic picture, this article proposes a number of coordinates which can give biolaw the necessary **features** to cope with a difficult, ever-changing and very specific dimension of human knowledge. Our proposal is that these coordinates can serve to build an open, updated and attentive law for 21<sup>st</sup> Century life sciences.

## 2. Anthropocene: Pros and Cons of Life Sciences and Biotechnology

Current human activity produces considerable effects, both positive and negative, on a global level. The geological age in which we are living has been defined as “the period during which human activity has been the dominant influence on climate and the environment”.<sup>2</sup> Anthropocene, in this perspective, is the term proposed by biologist Eugene F. Stoermer and used and popularized by the 1995 winner of the Nobel Prize for chemistry Paul Crutzen. As the main source of the deepest transformations of the globe, human population has influenced and altered the balance of the planet through, among others, a massive emission of carbon dioxide and methane, a severe reduction of tropical forests and biodiversity, the occupation of about 50% of the land by a population that has increased tenfold, the depletion of freshwater resources and fish and the massive use of nitrogen fertilizer in agriculture.<sup>3</sup>

Along with this negative impact on the earth’s balance, mankind has positively and radically progressed in the study and understanding of the biological, genetic and neurological dynamics and mechanisms of our bodies and minds, and of life itself.<sup>4</sup> The potential of these studies to improve human well-being is very promising and some applications of such knowledge are already underway. The scope of Anthropocene, then, may be applied to the potential impact of life sciences on our lives and on life itself.

Progress and developments in the field of medicine, for instance, have produced extraordinary benefits for most of the world’s population.<sup>5</sup> After being one of the incremental factors in the global in-

<sup>2</sup> This is the definition of the term Anthropocene in the online version of the *New Oxford American Dictionary* (accessed 2016-07-25).

<sup>3</sup> *Anthropocene: The human age*, *Nature*, 519, 144–147 (12 March 2015); S.L. LEWIS, M.A. MASLIN, *Geological evidence for the Anthropocene*, *Science*, 17 July 2015: Vol. 349, Issue 6245, pp. 246-24. See also the reconstruction of the human species as a super-predator in B. WORM, *A most unusual (super) predator*, *Science*, 2015 Aug 21; 349(6250):784-5. On the impact of biotechnology on society and the need to regain control, see S. JASANOFF, *The Ethics of Invention: Technology and the Human Future*, New York, 2016.

<sup>4</sup> The online version of the *New Oxford American Dictionary* defines *Life Sciences* as “the sciences concerned with the study of living organisms, including biology, botany, zoology, microbiology, physiology, biochemistry, and related subjects”. The *Life Sciences* page of *Wikipedia* lists 31 entries under the heading *Biology* and its branches, 29 entries under the heading *Medicine* and its branches and 34 entries under the heading *New and other life science types* (accessed 2016-07-23). For the purposes of this article, the main reference goes to sciences dealing with physical and psychological human wellbeing.

<sup>5</sup> In a century, life expectancy at birth in a number of countries has risen from around 50 years to more than 80. The main problem, due to causes ranging from the spread of HIV to poor availability of drinking water, consists in the lack of homogeneity at the global level. See, for example, the data provided by the OECD (<https://data.oecd.org/healthstat/life-expectancy-at-birth.htm>) or by the National Institute on Aging of the US Department of Health and Human Services (<https://www.nia.nih.gov/research/publication/global-health-and-aging/living-longer>) (both accessed 2016-07-25).

crease in life expectancy, biomedicine is now aiming for more and more sophisticated and ambitious targets, which, however, open an array of very sensitive and controversial issues.

Among these, for example, are: cognitive enhancement, which through the use of neurostimulators raises a number of problems that condense around a reductive vision of human intelligence<sup>6</sup>; the definition and patentability of human embryos after the changes that occurred in the Court of Justice case law<sup>7</sup>; the property of biological samples and genetic information, and the regulation of biobanks around the world; the access and limits for preimplantation genetic diagnosis and their use on a non-medical basis<sup>8</sup>; personalized or precision medicine that, alongside an increase in the efficiency of care, may also involve rethinking clinical trial principles as well as an escalation in the costs and a reduction in the number of sick persons treated.<sup>9</sup>

These areas, to which others could be added in the field of neuroscience or robotics for example, show how current developments of life sciences produce multiple points of contact with both traditional and novel bioethical and legal issues.

The genome editing tool CRISPR-Cas9 is one of the latest discoveries that has catalysed the attention of both specialized journals and the mainstream media on the ethical and legal limits of biotechnology and the necessary respect for individual rights, group interests and human dignity.<sup>10</sup>

Through an easily manageable and cheap genetic engineering technique, in which portions of DNA can be targeted, removed and replaced using artificial nuclease as "molecular scissors", a group of researchers at the University of Guangzhou in China applied CRISPR Cas9 to 86 human supernumerary and non-viable embryos. Their goal was to modify the gene responsible for  $\beta$ -thalassaemia. After 48 hours, 28 embryos out of the 54 survivors presented the desired change, part of them exhibiting,

<sup>6</sup> See for instance the opinion of the ITALIAN NATIONAL BIOETHICS COMMITTEE, *Neuroscience and pharmacological cognitive enhancement: bioethical aspects*, (<http://presidenza.governo.it/bioetica/eng/opinions.html>) (accessed 2016-07-25).

<sup>7</sup> *Oliver Brüstle v. Greenpeace*, October 2011, and *International Stem Cell Corporation v. Comptroller General of Patents, Designs and Trade Marks*, December 2014.

<sup>8</sup> On embryo selection based on the gender of the baby, see Arthur Caplan's interview with the *Wall Street Journal* in August 2015 (<http://www.wsj.com/articles/fertility-clinics-let-you-select-your-babys-sex-1439833091>). In countries such as India, the number of females under age 6 calculated for every 1,000 males (the so-called Child Sex Ratio: CSR) has over the past 20 years decreased from 945 (in 1991) to 918 (in 2011): see *Sex Ratios and Gender Biased Sex Selection. History, Debates and Future Directions*, published by UN Women in 2014 (<http://asiapacific.unwomen.org/en/digital-library/publications/2014/9/sex-ratios-and-gender-biased-sex-selection>).

<sup>9</sup> Published in October 2013 by the Food and Drug Administration, see the paper on *Paving the Way for Personalized Medicine* (<http://www.fda.gov/ScienceResearch/SpecialTopics/PrecisionMedicine/default.htm>).

<sup>10</sup> See H. LEDFORD, *CRISPR, the disruptor*, *Nature*, 522, 20–24 (04 June 2015) (<http://www.nature.com/news/crispr-the-disruptor-1.17673>); S. CAPORESI, G. CAVALIERE, *Emerging ethical perspectives in the clustered regularly interspaced short palindromic repeats genome-editing debate*, *Personalized Medicine*, 2016, 13(6): 575–586. Non-scientific reviews are also paying a lot of attention to the practice: on August 22 2016, *The Economist* published an issue dedicated to *Editing Humanity, the prospect of Genetic Enhancement*.

at the same time, a number of unexpected mutations. The researchers themselves said that the results revealed serious obstacles to using the method in medical applications.<sup>11</sup>

The publication of this research, conducted for the first time using CRISPR on human embryos, has ignited a heated debate among researchers, bioethicists and legal scholars on the ethical and legal legitimacy of the application of the new technique on human embryos. While there is general agreement on moving forward with basic and clinical research on the somatic line and on banning the transfer of treated human embryos in utero, the scientific community is divided on the application of the technique on spare, non-implantable human embryos.<sup>12</sup>

In any case, what is worth mentioning here is the need to combine scientific research, particularly when it touches on such sensitive issues as the source of life itself, with a fully aware and open ethical and legal debate. In some cases, philosophical and legal thought has created (and still creates) unreasonable obstacles to the legitimate freedom of research.<sup>13</sup> But this fact does not justify the exaggerations of saying that “the primary moral goals for today's bioethics can be summarized in a single sentence. Get out of the way”.<sup>14</sup>

These simplifications seem even more inappropriate if we recall a few recent cases in which genuine knowledge and human progress were considered at the bottom of the list of interests pursued by certain powerful sponsors.<sup>15</sup> It may also be worth mentioning the largest Health Care Fraud Settlement in U.S. History, in which “GlaxoSmithKline LLC (GSK) agreed to plead guilty and to pay \$3 billion [to the United States Department of Justice] to resolve its criminal and civil liability arising from the company's unlawful promotion of certain prescription drugs, its failure to report certain safety data, and its civil liability for alleged false price reporting practices”.<sup>16</sup> And in general terms, it is worth citing a recent report by the UK-based Nuffield Council on Bioethics on *The Culture of Scientific Re-*

<sup>11</sup> The results were published in the online version of *Protein and Cell* (11 April 2015). See also the news reported, for example, by *Nature* online (22 April 2015): D. CYRANOSKI, S. REARDON, *Chinese scientists genetically modify human embryos*.

<sup>12</sup> One of the most cutting-edge research is described in D. CYRANOSKI, *Chinese scientists to pioneer first human CRISPR trial. Gene-editing technique to treat lung cancer is due to be tested in people in August*, *Nature News* online, 21 July 2016 (<http://www.nature.com/news/chinese-scientists-to-pioneer-first-human-crispr-trial-1.20302>). See the National Academy of Science, Engineering, Medicine, *Human Genome Editing. Science, Ethics, and Governance*, The National Academies Press, 2017 (<https://www.nap.edu/catalog/24623/human-genome-editing-science-ethics-and-governance>).

<sup>13</sup> See criticism of IRBs and ethical committees in general in J. BARON, *Against Bioethics*, MIT Press, 2006.

<sup>14</sup> See Steven Pinker's interview with the *Boston Globe Today* summarized in M. COOK, *Disdain for bioethics ignites controversy*, *BioEdge*, 9 August 2015 (<http://www.bioedge.org/bioethics/disdain-for-bioethics-ignites-controversy/11516>).

<sup>15</sup> We are not mentioning Nuremberg or Tuskegee. We are referring to much more current unethical and illegal conducts such as ‘evergreening’ (*Novartis AG v. Union of India and Others*, 2013, 6 SCC 1), ‘pay-for-delay’ (the *Fentanil* case in which J&J and Novartis were fined 15 million Euro by the European Commission) or ‘non-disclosure agreement’ (see, for instance, S. GARATTINI, V. BERTELÉ, G. BERTOLINI, *A failed attempt at collaboration*, *BMJ* 2013; 347: f5354).

<sup>16</sup> Other details on the website of the US Department of Justice: <https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report>.

*search in the UK.*<sup>17</sup> Comprising interviews with nearly 1,000 scientists from different disciplines, the Council Report provides an assessment of the quality of scientific research. Its results include hardly optimistic conclusions in terms of competition, funding of research, assessment of research, research integrity and career progression and workload. Career pressure to publish only on High Impact Factor Journals, often fierce competition, some weaknesses in the peer review system, certain logics of financing and evaluation – concludes the report – lead to negative outputs such as the exaggeration of the results (headline chasing), less collaboration, loss of creativity and innovation, disincentives for multidisciplinary research. In conclusion, “Fifty-eight per cent of survey respondents are aware of scientists feeling tempted or under pressure to compromise on research integrity and standards, although evidence was not collected on any outcomes associated with this”.<sup>18</sup>

### 3. The match between law and life sciences

Taking into account a picture where life sciences and their applications are not always driven by the most authentic goals of human progress and wellbeing, the quoted appeal to guarantee them a space completely apart from the bioethics debate and legal rule is not convincing. On the contrary, it is possible to recall the very original goals of constitutionalism: protection of rights and limitation of powers, which nowadays must be extended far beyond the traditional three powers (the legislative, executive and judicial of Montesquieu’s doctrine) to a comprehensive approach that includes any form of power, whether it be social, economic or precisely scientific. In this perspective, the exercise of every power has to be combined with an equally strong dimension of rule of law and protection of rights. Nowadays, these constitutional principles, as well as democratic logics, prevent life sciences from being governed by mere self-regulation. If the law, as well as bioethics, has not always proved effective and balanced in dealing with science, on the other hand, science cannot find in itself its only limit.

In order to prevent the recurrence of the errors that have sometimes undermined the relationship between law and science, yet, it is necessary to single out a number of specific qualities that an effective and reasonable biolaw must assume. Indeed, life sciences and their applications represent objects with peculiar and uncommon characteristics which biolaw must respect and match on, at least, three different sides.

First, life sciences work on very difficult materials, whose understanding requires both scientific expertise and ethical sensibility. So, it is possible, and likely, that political and legal actors, not being equipped with specific scientific knowledge, find particular difficulties in understanding and ruling on such a complex subject matter. On the other hand, life sciences insist on very sensitive anthropological and philosophical issues, raising very complicated ethical and therefore cultural, social and politi-

<sup>17</sup> The most critical elements were summarized under five headings: Competition, Funding of research, Assessment of research, Research integrity, Career progression and workload. See NUFFIELD COUNCIL ON BIOETHICS, *The Culture of Scientific Research in the UK*, London, December 2014 (<http://nuffieldbioethics.org/project/research-culture/>).

<sup>18</sup> Quoting part of the conclusions of the finding of the research: <http://nuffieldbioethics.org/project/research-culture/the-findings/>.

cal, dilemmas. It may therefore happen, again, that legislators and courts have to open their procedures to more sensitive actors.

Life sciences, secondly, deal with a subject matter that develops in a very rapid and non-linear way. Driven by the scientific method, this part of human knowledge discovers results which are constantly tested, specified and maybe proven wrong by future studies. If uncertainty is physiological in life science progress, yet, it is particularly challenging in law, where obsolescence of rules and decisions threatens stakeholders' legitimate expectations and where equality expects a certain level of certainty and stability.

A third feature that makes life sciences and their applications a particularly complicated legal object springs from the fact that the described complexity makes them a very unsuitable matter to be ruled on by general and abstract principles. Differences from case to case are often due to small concrete characteristics of the bio-objects. And biolaw must recognize and take into account these differences, so as not to prejudice, with vague rules, the appropriateness and proportionality of the regulation.

Based on this three-fold picture, and within a doctrinal framework in which influential scholars have already indicated the most appropriate traits for contemporary legislation<sup>19</sup>, we will advance proposals indicating three properties of biolaw for the three indicated characters of life sciences – properties aimed at building a biolaw that is altogether open to both science and ethics, updated and attentive. In doing that, we will use the comparative method in order to provide food for thought for the overall refinement of a biolaw suited to 21st Century challenges.

#### 4. An open biolaw

The first of the proposed features deals with opening the process of rule-making and decision-making to both science and ethics. In this regard, comparative law offers a number of instruments through which the parliamentary assemblies and the courts can open their procedures, in order to get both a virtuous contamination with the scientific dimension and greater proximity to the philosophical and social sensitivities.

A first case in point is the French *Lois de bioéthique* adopted by the Parliament to include in the *Code de la santé publique* and keep updated (2011) a set of principles relating to biomedicine.<sup>20</sup> In France, the principles inspired by participatory and deliberative democracy (*esprit républicain, débat public* and *démocratie de proximité*) have been applied to the 2011 reform of the *Code*, which collected the results of actual *Etats Généraux de la bioéthique* assembled in order to allow the Parliament to legislate on the basis of “*non seulement une considérable somme d'études, de travaux de rapports et*

<sup>19</sup> “Law itself has limits that suggest deference and humility in considering whether and how to use it (...). Sound public policy requires evaluation of each legal tool to ascertain which one(s) can deal best with which problems of biomedical advance and to understand the limits of the ability of each legal tool and the entire legal system to regulate biomedical developments”: R.B. DWORKIN, *Limits. The Role of the Law in Bioethical Decision Making*, Indianapolis, 1996, 2. In general, see G. ZAGREBELSKY, *Il diritto mite. Legge, diritti, giustizia*, Torino, 1992, speaking about a mild law; P. ZATTI about a gentle law (<https://undirittogentile.wordpress.com/>).

<sup>20</sup> The inclusion goes back to 1994, modified in 2011: <https://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006072665>.

*produits par les différentes instances concernées, mais aussi du Préambule nécessaire d'une réflexion collective suscitant l'expression d'un accord ayant vocation fondé à être sur la reconnaissance de valeurs partagées".*<sup>21</sup>

While different scholars evaluated in different ways the substantial efficacy of the *Etats Généraux*, France remains the most significant experience, at least from a symbolic point of view, regarding the formalization of channels through which the Parliament's exposure to scientific data and social perceptions (upstream) may contribute to a greater legitimacy (downstream) of the law related to biotechnology.<sup>22</sup>

A second example of a legislative procedure open to the scientific and ethical dimension may be the British regulation on mitochondrial donation.<sup>23</sup> The two mitochondrial replacement techniques permit replacing of the mitochondrial DNA of an egg (or a zygote) taken from a woman carrying mitochondrial mutations with that of a "healthy" woman. In this way, these techniques would avoid the transmission of mitochondrial mutations through the maternal line which are responsible for mitochondrial diseases.

According to some experts, this practice is still imprudent and unsafe, as not yet sufficiently tested, as well as ethically problematic since it produces children with a father and two mothers (the one that gives the oocyte and the one who provides the mitochondrial DNA). Given the complexity of the issue, the British Parliament proceeded with a series of procedural steps aimed at acquiring both scientific information and ethical opinions. Before approving the techniques, the Human Fertilisation and Embryology Authority carried out three evaluations of the safety of the techniques (in 2011, 2012 and 2014) and a public consultation (2012). In addition, the Nuffield Council on Bioethics, an independent body that examines ethical issues in biology and bio-medicine, produced a report on mitochondrial replacement techniques and the Parliamentary office for science and technology (POST) published a note to favour the parliamentary debate.<sup>24</sup>

This kind of scientific and social consultative procedure, highly inclusive and structured, has become a constant in rule-making on sensitive and divisive issues in some countries.

In Britain, again, the Director of Public Prosecutions opened a public consultation in 2009, before deciding the conditions under which not to proceed against persons who had committed the crime of assisted suicide.<sup>25</sup> And the Australian National Health and Medical Research Council, in late August

<sup>21</sup> The quotation is taken from Minister R. BACHELOT's inaugural speech: <http://www.etatsgenerauxdelabioethique.fr/>. Among other, see B. REBER, *Introduction. Analyses des États Généraux de la Bioéthique, Le droit pénal, Arch. Philo. droit*, 2009, 53, 275.

<sup>22</sup> J.R. BINET, *La réforme de la loi bioéthique: commentaire et analyse de la loi n. 2011-814 du 7 juillet 2011 relative à la bioéthique*, Paris, 2012.

<sup>23</sup> The *Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015* was adopted by Westminster in February 2015 and entered into force on October of the same year. See S.A.M. MCLEAN, *Mitochondrial DNA Transfer. Some Reflections from the United Kingdom*, *BioLaw Journal*, 2015, II, 81 (<http://www.biodiritto.org/ojs/index.php?journal=biolaw&page=article&op=view&path%5B%5D=81>).

<sup>24</sup> See L. CRAVEN *et al.*, *Research into Policy: A Brief History of Mitochondrial Donation, Stem Cells*. 2016 Feb; 34(2): 265–267. All the information on the HFEA website: <http://www.hfea.gov.uk/9935.html>.

<sup>25</sup> In September 2009, when the Director of Public Prosecutions for England and Wales was debating the severity of the crime of abetting suicide, he opened an online public consultation, with nine questions. The consultation received more than 5,000 replies, from individuals and associations on both fronts, which were

2015, did the same before discussing the inclusion of the sex of the baby as a legitimate reason for embryo selection.<sup>26</sup>

In addition to these experiences, comparative law shows a large number of examples related to the assistance from technical bodies to legislatures when facing particularly complex issues from a scientific and ethical point of view. Among many others, worth mentioning here is the well known procedure that led the United States to change the legal definition of death. The new definition was first proposed by the ad hoc Committee of the Harvard Medical School and then implemented in the US and in the majority of national systems around the world.<sup>27</sup>

Laws on *assisted reproductive technology* (ART) are also usually the result of a comprehensive decision-making process that envisages the contribution of scientific committees: the Spanish *Ley de Reproducción Humana Asistida*, in its various versions (35/1988, 45/2003, 14/2006), has largely incorporated the recommendations of the *Comisión Palacios* at the beginning, and of the *Comisión Nacional de Reproducción Humana asistida* later<sup>28</sup>; the British *Human Fertilization and Embryology Act 1990* was written on the basis of the Warnock Report of 1984.<sup>29</sup> In this perspective, a recent comprehensive analysis of ART brings fresh comparative data confirming the importance of the reference to technical and scientific expertise in order to deliver fair, effective and legitimate laws<sup>30</sup>.

From this point of view, if, on the one hand, science as such cannot assume a direct normative role, on the other hand, the respect of its most commonly shared results may be seen as a constitutional commitment for legislatures.

Italian constitutional case law is a case in point. Dealing with a statutory ban on medical treatments that, according to the medical literature, could have therapeutic efficacy, the Court struck down the law: prohibiting an effective treatment, Parliament infringed on the fundamental right to health as

taken into account by the office in issuing a new Policy for Prosecutors in Respect of Cases of Encouraging or Assisting Suicide, which now recognizes a not always overriding public interest in favour of the prosecution. Materials and the text of the policy at [http://www.cps.gov.uk/publications/prosecution/assisted\\_suicide\\_policy.html](http://www.cps.gov.uk/publications/prosecution/assisted_suicide_policy.html).

<sup>26</sup> I. OLVER, *Why We Should consider Whether it's time to allow sex selection in IVF*, *The Conversation*, August 23, 2015 (<https://theconversation.com/why-we-should-consider-whether-its-time-to-allow-sex-selection-in-ivf-nhmrc-46399>). See in general M. SONIEWICKA, *Failures of Imagination: Disability and the Ethics of Selective Reproduction*, *Bioethics*, 2015, 29, 557.

<sup>27</sup> AD HOC COMMITTEE OF THE HARVARD MEDICAL SCHOOL, "A Definition of Irreversible Coma – Report of the Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death," *JAMA* 1968; 205(6): 337-340.

<sup>28</sup> The *Exposición de Motivos* of the 2006 Spanish statute acknowledges the *Comisión Nacional* as the body that fixed "las líneas directrices que debería seguir la nueva regulación y que esta Ley incorpora".

<sup>29</sup> Looking at the experiences mentioned, Italy is one example that does not provide any structured technical-scientific channels to assist Parliament. Law 40/2004 on Assisted Medical Reproduction is a paradigmatic case regarding the fact that, when legislation does not consider scientific data in the decision-making process, it will result in a highly ineffective regulation. The Italian Constitutional Court has intervened several times on the statute, correcting its most serious constitutional and scientific flaws. A general overview in <http://www.biodiritto.org/index.php/item/480-dossier-come-%C3%A8-cambiata-la-legge-40-2004-2014>.

<sup>30</sup> S. PENASA, *La legge della scienza: nuovi paradigmi di disciplina dell'attività medico-scientifica. Uno studio comparato in materia di procreazione medicalmente assistita*, Napoli, 2015.



provided for by Art. 32 of the Constitution.<sup>31</sup> The same declaration of unconstitutionality was adopted by the Court towards a statute that, imposing the transfer into the uterus of all created embryos (up to three), increased the risk for women's health.<sup>32</sup> The fundamental right to health, in these terms, inhibits the Parliament in enacting statutes both banning treatments that, according to medical literature, are effective and imposing treatments that, again according to medical literature, are dangerous. In this perspective, the results of medical sciences, as far as they are shared in specialized literature, determine the size and shape of the "right to health", providing legislatures with precise limits for their normative functions. Quoting the Italian Constitutional Court: "except when other rights or constitutional duties are at stake, it is not the legislator, as a rule, that is able to determine directly and specifically what are the therapeutic practices accepted, to what extent and under what conditions".<sup>33</sup> "In this regard, it is important to point out that the case law of the Constitutional Court has repeatedly emphasised the limits placed by scientific and experimental knowledge on legislative discretion, which are continuously developing and on which the medical state of the art is based: this means that, in matters concerning clinical practice, the basic rule must be the autonomy and responsibility of the doctor who, with the consent of the patient, makes the necessary professional choices".<sup>34</sup>

Based on this constitutional case law, which resembles other national experiences as well as the perspectives of the European Court of Justice and the European Court of Human Rights<sup>35</sup>, one may say that science (medical literature outcomes, particularly) has the ability to fill the content protected by the right to health, performing a function equivalent to an "interposed parameter of constitutional legitimacy". Laws prohibiting health treatments that science claims can be beneficial, as well as laws imposing treatments that science claims can harm people, are equally unconstitutional – not because they (directly) contrast scientific outcomes, but because this conflict reveals an (indirect) infringement of the right to health.

From this point of view, we can say that consideration of scientific data by the law is not only functional to its greater effectiveness and overall acknowledgment; it sometimes becomes, in a symbiotic relationship, a requirement for its very constitutional legitimacy.

<sup>31</sup> Decision no. 282/2002: declaration of unconstitutionality of the Marche regional statute prohibiting electroconvulsive therapy and psychosurgery. Art. 32 of the Italian Constitution reads as follows: "The Republic safeguards health as a fundamental right of the individual and as a collective interest, and guarantees free medical care to the indigent".

<sup>32</sup> Decision no. 151/2009: declaration of unconstitutionality of the article of the law on IVF imposing the transfer "in a unique and contemporary implant" of all embryos created in the procedure.

<sup>33</sup> Decision no. 282/2002.

<sup>34</sup> Decision no. 151/2009. This and other relevant decisions of the Italian Constitutional Court are translated in English: <http://www.cortecostituzionale.it/actionJudgment.do>.

<sup>35</sup> Among many, see the cases *Artogodan v. Commission* (ECJ 2002); *Hatton and Others v. The United Kingdom* (ECtHR 2003). On IVF, see the invitation to consider "dynamic developments in science and society" in the ECtHR decision *Case of S.H. and Others v. Austria* (app. No. 57813/00; 3 November 2011).

## 5. An updated biolaw

The second characteristic that qualifies biotechnology as a peculiar object of legal regulation concerns the speed of its development, with the consequence that its results change significantly over time. In order to consider fluidity and mobility, some legal systems usually provide for a set of legal tools, comprised in the temporary legislation category. This group includes a number of instruments such as emergency legislation, temporary-effects laws, sunset clauses, and experimental legislation. The last two instruments are of particular importance for biolaw. They both share the need to consider time in order to assure legal effectiveness. But they aim at this result using different strategies. While sunset clauses are characterized by limited duration and ex post evaluation, determining “the termination of a statute, specific provision, programme, or agency, unless there is solid evidence that the latter should be renewed for another fixed period”, experimental legislation “refers to laws or, more commonly, regulations (secondary legislation) which introduce rules in deviation of existing law for a fixed period, for a limited group of citizens or territory and which are subject to a periodic or final evaluation”.<sup>36</sup>

States like Israel or Rhode Island, in this perspective, enacted laws respectively prohibiting genetic engineering and reproductive cloning, and providing a fixed date to the expiration of which the laws would have no longer had effect.<sup>37</sup>

Alongside these first (strong) instruments connecting the effectiveness of the rule to the passage of time, there is a second (weak) model that simply invites reconsideration of the previously adopted legal regulation. France, adopting this softer approach, provided for a reevaluation charge of the *Lois de Bioéthique* currently in force to be carried out every seven years.<sup>38</sup> The Canadian Assisted Human Reproduction Act 2004, following the same logic, had to be reviewed by Parliament every three years.<sup>39</sup>

In general terms, these tools create a number of significant problems for some traditional legal categories.

Predictability and legal certainty respond to the need for continuity, which is antithetical to expiring or periodically changing regulatory measures. There emerges, in short, a contrast between legal certainty, on the one hand, and the need to have the most up-to-date rule in high-variability-rate scientific fields, on the other. This polarity is not new or unique to biolaw. “Law must be stable, and yet it cannot stand still” wrote Roscoe Pound already in 1923.<sup>40</sup> Unlike the typical use of such institutes in areas such as terrorism, war or economic crisis, however, sunset clauses and experimental laws in

<sup>36</sup> S. RANCHORDÁS, *Sunset Clauses and Experimental Regulations: Blessing or Curse for Legal Certainty?*, *Statute Law Rev.*, 2014, 1 (<http://slr.oxfordjournals.org/content/early/2014/02/11/slr.hmu002.abstract>).

<sup>37</sup> The General Authorization for the Processing of Genetic Data, issued by the Italian Data Protection Authority in 2007, provided for a one-year validity. The deadline was extended until 2011 and since then the Authorization is re-approved annually without substantial changes.

<sup>38</sup> In the previous version of the law the term, introduced because of a *Conseil d'Etat* opinion, was five years.

<sup>39</sup> In a more general perspective, in 2013 the UK Government issued a Better Regulation Framework manual advising the use of sunset and review clauses in a number of topics ([https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/468831/bis-13-1038-Better-regulation-framework-manual.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/468831/bis-13-1038-Better-regulation-framework-manual.pdf)).

<sup>40</sup> R. POUND, *Interpretations of Legal History*, Cambridge, 1923, I.

the field of life sciences are not used for exceptional circumstances or emergency and temporary conditions. They are tightly linked to a physiological and enduring character of the object to be ruled on, which is devoted to constantly changing over time.<sup>41</sup>

In this sense, it is possible to distinguish two types of temporary laws in the field of life sciences.

In the first model, the flexible nature of the content of the regulation is closely linked to a change in the scientific paradigm. In this case, the old law no longer makes sense because its object simply does not exist anymore, having been replaced by another, more accurate and advanced one. One could speak in this regard of a mobile reference to the results of science, whose discoveries invalidate the rules that were addressing objects overtaken by new research. An example of this phenomenon can be taken by the traditional Latin motto “*Mater semper certa est*”. Contemporary IVF techniques using gametes donors or surrogacy agreements, as well as the aforementioned practice of mitochondrial transfer, make the formula scientifically obsolete, and futuristic hypotheses of artificial womb or cloning could possibly complicate things.

A second type of temporary legislation is linked not to the expected scientific change, but to a supposed change of ethical and social environment. In this case, the regulation does not expire because its object does not exist anymore, but because it is assumed that, in time, social and political sensitivities may likely change. The mentioned French case of *Lois de Bioéthique* and the Canadian Assisted Human Reproduction Act, along with the current debate on the 14 days rule for embryo research, are good cases in point, also providing examples of combination of the two mentioned models.<sup>42</sup>

The two instruments mentioned are different in nature, effects and normative implications. Despite these differences, their meaning is equivalent and concerns, on the one hand, the need for a connection between law and scientific and cultural changes, and on the other, a precise choice in the exercise of legislative power. Using temporary legislation instruments not only leads to an updated law, but it also helps keep an open dialogue between different social, religious and ideological positions. It allows a law that is not shared today to be reconsidered and potentially modified in time, enjoying, in this way, the most extensive legitimacy by even different societal components. This strategy seems to be particularly appropriate for such sensitive and vexed issues as biotechnology: it does not set the ultimate result of a competition, declaring winners and losers, but creates the conditions for keeping alive a plural and politically responsible debate, also in the perspective of new negotiations and new results. Eventually, argumentation and persuasion may be stronger than the mere computation of votes.

<sup>41</sup> In general terms, S. RANCHORDÁS, *Sunset Clauses and Experimental Regulations: Blessing or Curse for Legal Certainty?*, above, 17, sees absolute stability as “impossible (and even undesirable) to achieve since, first, legislators and regulators do not possess complete information about all the required elements which can cause or solve the social problems requiring legislative or regulatory intervention; secondly, legislators are unable to eliminate the risk-factor which underlies legislation; thirdly, legislators are constantly confronted with the obsolescence of laws and the possible occurrence of mistakes in lawmaking. In addition, absolute certainty in legislation or regulation does not have a place in a world characterized by constant change”.

<sup>42</sup> On the contrary, the Italian Act no. 40/2004 on artificial reproduction techniques does not contain any temporary clause. Only the Guidelines provide for an invitation to periodic reconsideration, which, however, does not refer to a possibly changed cultural climate, but only to technical and scientific progress: “The guidelines are periodically updated, at least every three years, in relation to technical-scientific evolution”.

The time factor plays an important role on the judicial side as well. Mentioning just a few cases in the biotechnology field, the ECJ *International Stem Cell Corporation* decision (December 2014) is a case in point. Patentability, in this decision, has been extended to parthenotes, while in the precedent *Brüstle v. Greenpeace*, three years before, it was expressly excluded. The overruling was triggered by new, or more accurate, scientific studies that had ruled on their inherent inability to develop into human beings, “according to current scientific knowledge, a human parthenote, due to the effect of the technique used to obtain it, is not as such capable of commencing the process of development which leads to a human being... The mere fact that a parthenogenetically activated human ovum commences a process of development is not sufficient for it to be regarded as a human embryo”.<sup>43</sup> Conversely, the Grand Chamber of the European Court of Human Rights (decision *SH and Others v. Austria*) decided to disregard the relevance of the time factor.<sup>44</sup> The ban on heterologous fertilization contained in the Austrian law, which was consistent with the studies and the social sensibility registered in 1992 (the year of enactment of the Act), was considered compatible with the ECHR standards, through an interpretative logic that refused to consider the changes that have occurred in the meantime. The time factor was the object of a mere obiter dictum, in which the majority of the Judges just released a general warning: “the Austrian parliament has not, until now, undertaken a thorough assessment of the rules governing artificial procreation, taking into account the dynamic developments in science and society... Even if it finds no breach of Article 8 in the present case, the Court considers that this area, in which the law appears to be continuously evolving and which is subject to a particularly dynamic development in science and law, needs to be kept under review by the Contracting States” (pp. 117 and 118).

For this reason, the dissenting opinion written by Judges Tulkens, Hirvelä, Lazarova Trajkovska and Tsotsoria is personally more convincing: “In an area undergoing profound changes, both from a scientific and medical point of view and in social and ethical terms, one feature of the present case is the time factor. The decision of the Austrian Constitutional Court dismissing the application lodged by the applicants was adopted on 14 October 1999. In that decision, the court observed itself that “[t]he choices the legislature [of 1992] had made reflected the then current state of medical science and the consensus in society. It did not mean, however, that these criteria were not subject to developments which the legislature would have to take into account in the future” (see paragraph 22 of the judgment). The application was lodged with our Court on 8 May 2000 and the Chamber judgment was adopted on 1 April 2010. In these particular circumstances, we find it artificial for the Court to confine its examination to the situation as it existed when the Constitutional Court gave judgment in 1999 and in the context at the time, thus deliberately depriving a Grand Chamber judgment, delivered at the end of 2011, of any real substance”.<sup>45</sup>

<sup>43</sup> Case C-364/1, *International Stem Cell Corporation v. Comptroller General of Patents, Designs and Trade Marks*, Judgment of 18 December 2014; Case C-34/10, *Oliver Brüstle v. Greenpeace*, Judgment of 18 October 2011.

<sup>44</sup> Case of *S.H. and Others v. Austria* (app. n. no. [57813/00](#)) 3 November 2011.

<sup>45</sup> Case of *S.H. and others v. Austria* (appl. no. 57813/00), 3 November 2011, Joint Dissenting Opinion of Judges Tulkens, Hirvelä, Lazarova Trajkovska and Tsotsoria.

## 6. An attentive biolaw

In addition to being open and periodically reconsidered and updated, an efficient and balanced biolaw, tuned on 21st Century biotechnology, should pay particular attention to the specific characteristics of individual cases. Medicine and life sciences in general, in fact, deal with cases that may differ from one another for minimal but nevertheless critical traits, which must be considered by the law so as to avoid discriminatory and unreasonable solutions.

The refusal of a life-saving treatment expressed by a patient who has needle phobia, for instance, can (and perhaps must) be considered differently from that of a Jehovah's Witness, and differently again from that of a suffering patient with a terminal disease. And to what extent should the desire not to be fed of a girl with anorexia, or the wish of a person with dysmorphic disease to have her legs removed, be respected?<sup>46</sup>

Again, the clinical situations of infertile women are very different: any general principles can underestimate such distinctions and hence lead to detrimental and disproportionate legal treatments. For this reason, for instance, Article 14 of the Italian law on artificial reproductive technique (the already criticized Act no. 40/2004) has been considered unconstitutional where it was prohibiting the creation of "a number of embryos greater than that strictly necessary for one single and simultaneous implantation, and in any case not more than three".<sup>47</sup> The Italian Constitutional Court pointed out that the chances of success of the treatment vary "in relation to both the characteristics of the embryos and the subjective conditions of the women who undergo the procedure of medically assisted procreation". Given the risks due, on the one hand, to a repetition of hyperstimulation cycles in the case of implant failure and, on the other, to those of multiple pregnancy in the case of implantation of all embryos, the imposition of a unique rule, valid for every situation, was incompatible with the fundamental right to health of women (art. 32 of the Constitution). The law, in fact, did not leave "the doctor any possibility to make an assessment, on the basis of the most up-to-date and accredited technical and scientific knowledge, of the individual case under treatment, with the resulting specification on a case-by-case basis of the numerical limit of embryos for implantation which is considered appropriate in order to ensure that a serious attempt at assisted reproduction is made, and reducing to a minimum conceivable the health risk to the woman and the foetus" (p. 6.1). By imposing the creation of a number of embryos equal to three "in the absence of any consideration of the individual conditions of the woman", the provision infringed the constitutional principles of reasonableness and equality.

Another example, among many, of disregard of law 40 for the specific features of different cases might be the absolute prohibition of access to ARTs for couples who did not present problems of ste-

<sup>46</sup> See I. GOOLD, J. HERRING, *Great Debated in Medical Law and Ethics*, Palgrave, 2014, 2 ff.

<sup>47</sup> Italian Constitutional Court, decision no. 151/2009

([http://www.cortecostituzionale.it/documenti/download/doc/recent\\_judgments/CC\\_SS\\_151\\_2009\\_EN.pdf](http://www.cortecostituzionale.it/documenti/download/doc/recent_judgments/CC_SS_151_2009_EN.pdf)).

The Unique exception provided for by the Act was so restrictive as to be unworkable: "When the transfer of embryos in the uterus is not possible for serious and documented reasons of force majeure concerning the health status of women, which is not foreseeable at the time of fertilization, the cryopreservation of embryos is permitted until the date of transfer, to be carried out as soon as possible" (art. 14, third par.). On the flaws of Act no. 40/2004 see, among others, V. FINESCHI, M. NERI, E. TURRILLAZZI, *The new Italian law on assisted reproduction technology (Law 40/2004)*, *J Med Ethics* 2005;31:536-539.

rility or infertility.<sup>48</sup> This rule excluded from the treatments couples with HIV. This provision exposed the components of the couple, and in case of pregnancy the foetus, to a very high risk of contagion due to sexual contact. This risk could have been successfully limited through a "sperm washing" to be performed within an artificial reproduction, which was however prohibited since HIV does not cause sterility. In order to keep intact, although only formally, the absolute nature of the prohibition, while allowing the use of ART to protect partner and foetus, the guidelines enacted by the Ministry performed real interpretive acrobatics, considering that the use of contraceptive precautions (i.e. a condom, which an HIV-carrying person should wear in order not to contaminate their partner) as a tool causing sterility.<sup>49</sup>

These examples show that the objects of medicine and life sciences have a number of characteristics that distinguish each case from another – and which the law should take into account in order to provide proportionate and balanced solutions.<sup>50</sup> To reduce the costs of "general and abstract" laws, some legal systems have chosen a governance strategy which combines the (relative) certainty of legislative instruments, as regards the general principles, with a high degree of flexibility in their implementation and enforcement.

Both in France and in the UK, access to ARTs is overseen by independent authorities (respectively, the *Agence de la biomédecine* and the Human Fertilization and Embryology Authority) with the tasks of integrating and enforcing the legislative principles (through regulations, guidelines, codes of practice) and to grant licenses for individual treatments.

The rule-making and adjudication functions vested by these authorities permit them to balance conflicting interests in considering very complex situations, from the point of view of both the techniques used and their possible consequences. This way, they are entitled to carefully consider the specifics of each concrete case, giving them reasonably flexible and narrowly tailored solutions.

It is natural for the judicial power to carefully consider the specifics of every single case. Yet, it is particularly significant to see how judges deal with general questions such as the definition ones.

In *International Stem Cell Corporation*, quoted above, the Court of Justice does not set the definition of 'human embryo' according to an absolute formula. After indicating the guiding criterion consisting in the "inherent capacity of developing into a human being", the ECJ entrusts the single national courts with the task of determining "if, in the light of current scientific knowledge, that ovum does not, in itself, have the inherent capacity of developing into a human being" (p. 38).

This logic is not isolated but emerges in a number of legal systems. Dealing with the legal framework for transsexualism, abortion and transplantation, for instance, an Italian legal scholar writes about two possible different approaches.<sup>51</sup> The first one is a top-down perspective which moves from a

<sup>48</sup> The blanket prohibition has been struck down by the Constitutional Court, decision no. 96, 14 May 2015.

<sup>49</sup> The Guidelines go as follows: "the high risk of infection for the mother or the foetus is in fact, in objective terms, an impediment of procreation, by requiring the adoption of precautions that result necessarily in cause of infertility, to be included among the cases of severe male infertility to be ascertained and certified by medical act".

<sup>50</sup> In general, J. KATZ, *Can principles survive in situations of critical care?*, in J.C. MOSKOP and L. KOPELMAN (eds.), *Ethics and Critical Care Medicine*, Dordrecht, 1985, 41-67.

<sup>51</sup> P. VERONESI, *Il corpo e la Costituzione. Concretezza dei casi e astrattezza della norma*, Milano, 2007, 285 ff.

general, ready-made idea of what is good for everybody, regardless of individual aspirations and specific interests. The second approach is bottom-up, and focuses on the single person, on the specific problems of her concrete existence, starting from the very personal place where interests and desires come from. This latter approach combines attention to individual needs with legal flexibility and concreteness, paving the path to a balancing of interests which is much more compatible with the constitutional principles.

## 7. Threats and opportunities

A number of other examples might be used to illustrate how 21st Century biolaw should be open, updated and attentive, in order to respect the complexity, fluidity and particularity of its object. And a number of specific threats cannot be hidden in this proposal. As mentioned earlier, any of the three features proposed also present risks for the legal systems.

First, opening the decision-making process too much to technical parties such as scientific bodies or independent authorities might undervalue the very reasons for Parliamentary democracy, leading to non-representative procedures and factional results. And it could also represent a channel for substituting general interests in favour of a biased selection of assets, driven by players in a conflict of interest. Changing the law depending on every variation in the public moods and emotions or on the results published in the latest issue of a scientific journal, secondly, could undermine any residue of legal certainty<sup>52</sup>. And biolaw might become utterly unpredictable, evoking the “dog-law” Jeremy Bentham used in order to criticise Judge-made law as such. Third, a law which is just tailored to every single case could, again, jeopardize any certainty and predictability, betraying the very essence of the principle of equality. It could become an unprincipled and capricious tool in the hands of potentially unchecked authoritarian powers.

As usual, the problem is ‘where to draw the line’ between the physiology of a responsible exercise of attention to the object to be ruled on and the pathology of a despotic and undemocratic use of power. The relationship between law and life sciences has not always been marked by balance and mutual understanding. An increasingly positive connection is needed to the extraordinary developments of life sciences. Focusing on opening, updating and fine-tuning the law on their specific features, following the subsidiarity principle (in which anyone performs properly their regulatory and control duties), may trigger a process of mutual integration that can gain effectiveness, respect and legitimacy for both the law and life sciences.

<sup>52</sup> H. GOTTWEIS, B. PRAINSACK, *Emotion in political discourse: contrasting approaches to stem cell governance in the USA, UK, Israel and Germany, Regenerative Medicine*, 2006, 1(6), 823-829.