

# GLOBAL LAW AND NATIONAL LAW IN LIFE SCIENCES AND TECHNOLOGY: SELECTED INSIGHTS AND PERSPECTIVES

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## *Abstract*

The essay briefly addresses dynamics emerging at the crossroads between legal phenomenon and life sciences. In particular, will be explored: the increasing “multilevel” and “transnational” dimension of the law applied to the questions posed by the biosciences; the evolution of the elements used to qualify the juristic personhood as a result of bioengineering in intervening at the beginning and at the end of human life and in creating synthetic organisms; the rethinking of the fundamental values (in Europe and in the U.S.) of autonomy, dignity, and pursuit of happiness facing the powerful capabilities provided by life-sciences in a “disenchanted world” where both the pluralism of moral thoughts flourished and the individualism in respect of one’s life-choices bloomed. Finally, a reference will be made also to the “social dimension” of the autonomous health choices: a perspective once tarnished but now rediscovered as the consequence of the fight against the Covid-19 pandemic.

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## 1. Introduction

This brief essay aims to present some introductory remarks about the multiple intersections between global law and national law under the specific perspective of the advance of life sciences<sup>1</sup>.

In particular, three points will be addressed (and a “follow up” will be lastly added): a) the multilevel and transnational characters of the legal phenomenon applied to life science; b) the vagueness of the contours of human legal personhood that the advancement in life sciences contribute to determining; c) the relationship between the principles of autonomy, human dignity and pursuit of happiness as applied to the new potentialities discovered by life science in realizing individual desires and expectations.

Of course, many other aspects of the interaction between life sciences and the law might be opportunely analyzed, including, for example, the rules on scientific and technological research and patenting or the reflection on how the scientific expertise might be relevant in the law-making process for adopting new statutes on the displacement of biomedical technologies or on compelling health interventions, such as vaccination (the so-called “scientific limit” to the parliamentary political discretion: Italian Council of State, No 7045/2021).

This essay, therefore, has no claim to completeness or exhaustiveness. Therefore, the reader is asked to be quite indulgent. Though, the relationship between law and the sciences of life is so complex and multisided, that rivers of ink would not be enough to cover it entirely and thoroughly.

## 2. The Emerging of the “Biolaw” at the Crossroads between the Law and the Life Sciences

Just to start, it is quite obvious how the disruptive progress of the life sciences (and their related technologies), joined with the

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<sup>1</sup> The text roughly draws and in many points adjourn and complements what has been told orally during the panel: “*Science, Technology and the Law*”, within the 1st “*Italian-American Dialogues on Constitutionalism of the 21st Century – Global Law vs. National Law?*”, under the aegis of the University of California at Berkeley, the University of Bologna and the University of Parma (October 10-11th 2019).

development of the information and digital sciences (and their related technologies) has deeply changed the world we are living in. The human being disposes, today, of many possibilities of choices to intervene in manipulating living processes, human and non-human, at the beginning and the end of life (and also in every other stage of the living existence).

In the contemporary era, society is experiencing various transitions, two of which have significant implications for human health: the “biomedical transition” and the “digital transition”. These transformations are reshaping the landscape of healthcare and influencing the ways in which health is understood, monitored, and managed.

For example, today, in intensive care facilities, we may use powerful devices able to resuscitate and to sustain vital functions in bodies, which, in a not too far past, would have become corpses quickly. We may also use different *in vitro* techniques to generate new babies for the benefits of parents affected by situations of insuperable infertility just a few decades ago. New genetic techniques, such as CRISPR/Cas9's, or new genetic products, like OGMs or synthetic DNA, are opening unprecedented capability of tailor-manipulating the very code of life. The neurosciences are trying to understand profoundly and, eventually, to change radically the same human brain – one of the most complex “object” of the Universe and the organ that contributes to making us humans – opening the path to possible, futuristic reprogramming of the neural circuits of memory, cognition, emotions. New tridimensional clusters of cells, cultivated by engineered stem cells (embryonic or induced by adult stem cells), are manufactured to recreate portions of tissues – the so-called “organoids” – which are able to mimic the corresponding *in vivo* organ. They may be used for sophisticated experiments or auto-transplants. Biocomputing, powered by artificial intelligence, may open the way to individualized medicine, while new types of nanomaterials will realize highly sophisticated implants making possible forms of “cyborgs,” which were before no more than sci-fi imaginations. Brain-computer interfaces (BCI), such as the well-known “Neuralink”, and brain implants, like deep brain stimulators (DBS), are creating new possibilities for treating neurological impairments or disorders – including communicative, cognitive, and motor

challenges – within the medical field; additionally, these technologies are enhancing the capabilities of individuals without health issues, enabling advancements in activities such as piloting, gaming, working, and home automation, among others. And the examples might continue.

If the life sciences and technologies are so impacting the human existence, realizing a new era, where artificial and natural components are so closely intertwined, the law, precisely as a phenomenon created by the humans for the humans and their environment (“*Cum igitur hominum causa omne ius constitutum sit*” in *Digesta*, 1.5.2, *Hermogenianus*), could not remain unaffected. Indeed, a new area of legal studies and practices has been developed – the so-called the Biolaw – dedicated to regulate the development and the use of sciences and techniques in genetics, biochemistry, cell biology, reproductive biology, evolutionary biology, ecology, neuroscience, and the behavioral sciences.

### 3. The Multilevel and Transnational Dimensions of Biolaw

One of the remarkable aspects of the Biolaw seems to be its *multilevel* and *transnational* “constitutional” dimension (where, of course, here “constitutional” refers not only to the sources of law formally considered as “constitutions” – which are not present at supranational level – but also to those principles, values, rights, general rules that are of “constitutional nature” and which composes the emerging trends of global constitutionalism).

Of course, also the *national level* cannot be underestimated in the evolution of Biolaw. It is up to the *national* Constitutions and legal traditions, indeed, to define the fundamental framework within which the case-law, the legal debate, and the new legislative provisions must evolve in the matter of life sciences. The cultural traditions, roots, and values involved in the bioethical questions find primarily in the *national law* their legal environment in terms of legal structures.

In Italy, for example, the Constitution (precisely: Article 2, Personalist principle, and general recognition of human rights; Article 3, Equality principle; Article 13, personal liberty; Article 32, right to health) has been one of most relevant sources of Biolaw (jointly with the Civil Code: Article 5, about the ban on auto-mutilations, or Articles

1218 or 2043 *et seq.*, about the breach of contract and tort in the medical relationship, and the Criminal Code: Articles 575 *et seq.*, about the crimes of assisted suicide, mercy killing, medical malpractice; and of course jointly also with the other provisions about informed consent and advance directives: Act No 219/2017, or about *in vitro fertilization*: Act No 40/2004, or about transplants: Act No 91/1999, or about the legal criterion of death: Act No 578/1993, and so on...).

However, the same phenomenon, we see in other legal areas nowadays, due to the present globalized world – i.e., the development of general or harmonized rules at the international and global level – is also present in Biolaw.

Indeed, biomedicine does not vary from one country to another one (except, of course, in terms of financial resources or types of medical devices, but that is a matter of national economy and state budget, and not of life sciences). Moreover, the same scientific enterprise is, more and more, connected across the national boundaries by the multiple forms of cooperation between different research groups displaced in several Countries. There are practices, like “*bio-dumping*” – the intentional lowering of ethical or legal standards in one country as to unfairly increase, in that specific country, the research potentials in biology and medicine – and of “*bio-tourism*” – the opportunity to travel abroad, just to find the place where the rules are more favorable to the satisfaction of personal desires in using biomedical technologies – which creates socially unsustainable inequalities. There are complex issues of worldwide magnitude, even more in a structurally globalized world, such as scientific competition between superpowers, the spread of diffusive diseases, human genomics, environmental issues, and so on. There is also the sensitive question of ensuring, by an outside cogent legal framework, the adoption and the respect of human rights face to face the most sensitive types of scientific research or usages of life technology’s powers, in those countries where there are not adequately democratic regimes or the rights of the individual are undervalued or not effective.

All these factors have pushed and still push for the development of legal rules at the *supranational* and *international* level, on biological and medical sciences and technologies.

As for the *supranational level*, in Europe, it is noteworthy the European Union Charter of Fundamental Rights (2000), which Articles

1 and 2 protects human dignity and life (preeminent, of course, in the legal debate on life sciences and technologies), and which Article 3, sect. 2 regards the biomedicine explicitly. Many are the EU regulations applicable concerning the life sciences and technologies. Just to provide a couple of examples, the European Union has adopted uniform rules for clinical trials (Regulation No 536/2014) and medical devices (Regulation No 745/2017) or for health data (which are foremost sensitive: Regulation No 679/2016, GDPR). It might also be mentioned the European Convention on Human Rights (1950), which Article 2 – that protects the right to life – and Article 8 – that safeguards right to privacy, intended as the right of each person to be respected in her individual autonomy against state’s intrusions, except in narrowed and qualified cases of compelling state interests – had been applied in many cases involving embryos, *in vitro* fertilization, freedom of scientific research, end-of-life issues. The same Council of Europe, which takes the responsibility to implement the ECHR, also promoted the adoption of a Convention on Human Rights and Biomedicine (1997), dedicated explicitly to the definition of standard protection for human rights in the field of medical and biological developments. Numerous are the resolution adopted by the Parliamentary Assembly of the Council of Europe on matters involving life sciences (such as, for example, the Resolution No 613/1976 and the Recommendation No 779/1976 on the rights of the sick and dying, or the Recommendation No 1418/1999 about the Protection of the human rights and dignity of the terminally ill and the dying, or the Resolution No 1859/2012 about euthanasia).

For the *international level* it is worthy of mention, for example, the so-called Nuremberg Code (1947), where the universal principle of clinical ethics, based on the informed consent of the individual were reaffirmed in the aftermath of the II World War, following the atrocious experiments conducted by the Nazi doctors. The World Health Organization’s Constitution (1946) contains no less than the universal definition of the same “health,” intended as a state of complete wellbeing also social and relational, and not only as of the absence of illness or infirmity. The United Nations Universal Declaration of Human Rights (1948) contains provisions referable also to the life sciences’ field, such as the principle of human dignity and liberty (Article 1), the right to life and liberty (Article 3), the right to be

recognized as a “legal subject” vested of rights and deserving of protection (Article 6). The UN International Covenant on Civil and Political Rights (1966) affirms the right of health (Article 12). Also, the United Nations Organization for Education, Science, and Culture (UNESCO) has adopted relevant – even if not full binding – declarations specifically devoted to promoting the protection of human rights face the advance of life sciences: the Universal Declaration on Human Genome and Human Rights (1997), the International Declaration on Human Genetic Data (2003), the Universal Declaration on Bioethics and Human Rights (2005).

However, the relationship between life sciences and legal phenomena should not be considered as limited only to those aforementioned legal sources. Indeed, in parallel with the above *multilevel dimension* (international, supranational, national legal rules on life sciences and technologies), the Biolaw is also characterized by a sort of “*transnational*” dynamic, which is flowing and flowering “horizontally” across the nations’ porous boundaries, making a country permeable to legal solutions invented and adopted abroad.

As aforesaid, the advance of life sciences and technologies does not differ too much across the developed areas of the world. As a consequence, when, in a certain country, arise a case that happened akin in another country, the legal (and ethical) questions might be the same. And if the two countries share a similar, or converging system of juridical values and rights, the resemblance of the case happened in one country spur the state powers (mainly, the judges, also encouraged by the activity of the lawyers and the legal doctrine) to have a look outside the national frontiers, trying to find in the other country’s legal framework tips and solutions. In cases involving the usage and the limits of biomedical resources (such as transplants, genetic engineering, end-of-life decision-making process, *in vitro* fertilization, neuroscientific pieces of evidence), the courts are favorable to cite legal principles affirmed or shaped by other courts in different jurisdictions. For example, in Italy, the Court of Cassation, No 21748/2007, has cited the judgments of the United States Supreme Court, *Cruzan v. Missouri Department of Health*, 497 US 261 (1990) and of the New Jersey Supreme Court, *In re Quinlan*, 70 NJ. 10, 355 A.2d 647 (NJ 1976) in an Italian case regarding the end-of-life decision-making process of an incompetent patient, and in a subsequent case regarding the crime of assisted

suicide in a medical context, the Italian Constitutional Court, No 135/2024 has widely cited the precedents of other European and non-European Supreme or Constitutional Courts, such as the German *BundesVerfassungsGericht*, 26 February 2020, No 2 BvR 2347/15 (*et seq.*), the Austrian *VerfassungsGericht*, 11 December 2020, No G 139/2019-71, the Spanish *Tribunal Constitucional*, 22 March 2023, No 4057/2021, the Supreme Court of Canada, *Carter v. Canada*, 2015 CSC 5, or the UK Supreme Court, *R (Nicklinson et al.) v. Ministry of Justice*, [2014] UKSC 38.

The “intra-circulation” of legal solutions and rules across the national boundaries, which contributes to the *transnational* dimension of the Biolaw, is also encouraged by other types of rules, adopted outside the traditional circuit of the political lawmakers, or the judiciary. Those rules, in the form of ethical codes, best practices, clinical guidelines, are shaped, in the first place, by the same professionals (physicians, scientists, researches, ...) through their associations which are representatives of many different Countries, and therefore “transnational”. Afterward, those rules, born originally outside the legal framework, become *formants* or *components* of the same legal framework, as *soft-law*: a flexible form of regulation, subject to revision by physicians and health professionals, and used by the courts as to interpret as instruments to interpret open-clauses (such as “health,” or “good clinical practices,” or “physical integrity,” or “autonomy”) in current laws or Constitutions.

About those “transnational” documents, one may refer to the statements adopted by the World Medical Association: the Declaration of Geneva, (1948, latest rev.: 2017), based on the Hippocratic Oath, the International Code of Medical Ethics (1949, latest rev.: 2006), on physicians’ duties, the Declaration of Helsinki (1964, latest rev. 2013) on clinical trials, the Declaration on euthanasia and physician-assisted suicide which have banned those interventions. Other documents that might be cited are the *Belmont Report* (1979), drafted by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which has posed the ethical principles of respect for the integrity and of balancing risk/benefits, or the Good Clinical Practice, detailed by the International Council for Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, which has inspired EU legislation. The Steering



Committee on Bioethics (CDBI) of the Council of Europe have promoted general ethical guides, such as the Guide for Research Ethics Committee Members (2010), the Guide on the decision-making process regarding medical treatment in end-of-life situations (2014), the Guide for the implementation of the principle of prohibition of financial gain with respect to the human body and its parts from living or deceased donors (2018). There are also the Codes of Medical Ethics adopted by national medical associations (in Italy, FNOMCeO, 2014, latest rev. 2020) and the reports and guidelines approved by the national bioethical committees.

#### **4. The Blurring Contours of the Legal Personhood in Biolaw**

The advance of life sciences and techniques, precisely because of its capacity to artificially create or sustain human life, at the beginning and the ending, it is having a tremendous impact on the traditional boundaries of human legal personhood.

For centuries, the natural boundaries of human life, in its intimate components, remained without any notable change. Therefore, at least until recent decades, it was still acceptable to argue that the boundaries of human life – the birth as well as the death – should be considered, by the legal phenomenon, nothing more than mere natural events in respect of which nothing particularly complicated had to be established by the same law (*“Der Tod als die Grenze der natürlichen Rechtsfähigkeit ist ein so einfaches Naturereignis, daß derselbe nicht so wie die Geburt eine genauere Feststellung seiner Elemente nötig macht”*: Carl Frederich von Savigny, *System des heutigen Römischen Rechts* (1840), vol. II, § 63).

On the contrary, today, for example, the death could be avoided – of course not always (we are still mortal beings...) – by life-saving and life-sustaining supports, making the prolongation of life something “artificial.” That has brought the law to adopt, over the last decades, different definitions of death, and therefore of cease of legal personhood, according to the same intensive care’s evolution in resuscitating and recovering patients.

For example, the traditional definition of death, adopted by the classical thanatology, and based on the cessation of the breath, became outdated after the invention of the artificial ventilator that made it

possible to support the lungs indefinitely. The definition of death based on the irreversible cardiac-arrest becomes questioned when there were invented and applied the cardio-pulmonary machine, the extracorporeal circulation, the transplant of heart. All those advances in biomedicine, in fact, made it possible to support vital functions, prolonging life, even when the hearth has been stopped or has to be transplanted. Therefore, it has been deemed appropriate to identify in the brain, the organ whose irreversible and total failure implies having crossed the border of death (*Ad Hoc Committee of the Harvard Medical School to Examine Brain Death*, 1968). However, also this last criterion is today sometimes disputed. For someone, the legal criterion of death should be anchored exclusively to the irreversible shutdown of a portion only of the brain: the cortex, as the unique seat of our higher typical human features, like consciousness. They argue that because the individuals, who do not have any possibility of self-awareness, are continuing to function only in their “metabolism,” thanks to machines, they might be considered, at least legally, as dead. For someone else, on the contrary, we cannot be sure that the persons without an active brain-cortex — the so-called “*vegetative state*” — cannot have “feelings,” and the same diagnosis of that condition is sometimes very difficult. And, in any case, they argue that the human being cannot be reduced “only” to his higher cognitive functions.

In any case, whatever the outcome of this debate, and the reflexes that discoveries on the brain by neurosciences could have in the next future, all this shows how the ultimate boundary of the human legal person (*death*), once “natural” and “indisputable,” has “moved” following the advance of biomedicine.

And there is even more. Italian Act No. 10/2020, which addresses the donation of cadavers for scientific research and medical education, explicitly establishes that the deceased body is, in itself, a subject of legal protection. This marks a significant shift, as it indicates that current legislative efforts recognize that even after life has ended, a human being, though having lost *legal personhood*, retains a form of “*subjectivity*.” It is this *legal subjectivity* that ensures the corpse is not merely perceived as an “*object*,” but rather that it holds an inherent *status* connected to the individual it represents, thereby deserving protection from misuse.

Even birth is no more just a simple natural occurrence. It might be, in fact, the result of the precise choice of intervention that uses manipulative genetics. The process of generation has become, in some instances, mostly artificial. The *in vitro fertilization* procedures have made it possible to make manipulations on the embryos in various ways, opening the moral and the legal question of their status and the protection those embryos might deserve since the conceiving.

That has dragged, of course, the problem of when and under which conditions, the legal personhood might commence, even before the traditional moment of birth – as the detach of living, even if not lively, fetus from the uterus – and therefore, what should be the legal status of the embryo.

For example, the European Court of Human Rights affirmed the principle that human embryos *cannot be reduced to mere “possessions,”* according to Article 1 of Protocol I of the same convention (European Court of Human Rights, No 46470/11, *Parrillo*). Therefore, according to the Court, even if they might not be appropriately considered as vested of legal personhood, the embryos should certainly not be regarded as mere “objects.” The Court of Justice of the European Union reiterated the principle that to consider a specific entity a human embryo – *not* patentable in light of the dignity principle according to the Article 6, Sect. 2 (c) Directive n. 98/44/EC and to the Article 1 of the EU Charter of Fundamental Rights – it is necessary the cells possess the inherent capacity of developing into a human being (EU Court of Justice, No C-36/13, *International Stem Cell Corporation* and No C-34/10, *Oliver Brüstle*). Under that point of view, not *all* the results of genetic manipulations using human re-engineered cells might be considered embryos and, therefore, worthy of dignity as human beings are. The Italian Constitutional Court has considered the embryo as an entity that has, in itself, the origin of life and, consequently, has dignity and some constitutionally relevant rights under Article 2 of the Italian Constitution (although in a stage of development not yet defined by law and that has not been unanimously ascertained by scientists: Italian Constitutional Court, No 84/2016). The same Court also affirmed that an embryo has a certain level of legal subjectivity related to the genesis of life inside it (Italian Constitutional Court, No. 229/2015). At the same time, the legal safeguarding of the fetus (and of the embryo) cannot be considered equivalent to the legal protection

of the mother. According to the Italian Constitutional Court, the fetus (and the embryo) is not yet a full legal person, whereas, on the contrary, the woman holds full legal personhood (Italian Constitutional Court, No 27/1975). An analogous argument – that the fetus is not a “person” even if it is not an “object” – has been used, as known, by the U.S. Supreme Court in *Roe v. Wade* (410 U.S. 113 (1973)), before the overruling by *Dobbs v. Jackson Women’s Health Organization* (597 US 2015 (2022)), and by the Supreme Court of Canada in *Tremblay v. Daigle* ([1989] 2 S.C.R. 530).

All those cases seem to reveal a sort of tendency in favor of the recognition of the dignity and of a degree of legal “subjectivity,” even if *not full legal personhood*, also to not-yet-born human entities. At least, if those not-yet-born entities possess the principle of human life, and if they have a recognizable capability to self-develop into a human being (of course, with the support of a uterus or an incubator).

All the above reveals how the boundaries of human legal personhood, also for the beginning (*pre-birth*), are now “moving.”

But there is even more.

Although it might be just futuristic, indeed, one shall not underestimate the results of some other experiments in life sciences, that might pose further questions about the legal personhood of certain biological entities.

Apart from the case of chimeras or hybrids (generally forbidden by the law) and of artificially intelligent machines (which are *not biological entities*), is the creation of the “organoids” that is opening a problematic scenario. In particular, it is one type of organoid that could pose the most difficult questions: the *cerebral organoid*. It is true that, until today, the development of these human brain organoids has not yet reached the threshold of any form of sophisticated human sensitivity or intelligence. However, one side, the brain organoids today realized, are already able to generate some brainwaves, which are quite similar to human brainwaves at a particular stage of fetus’ development; and we cannot exclude for sure that they might “feel” forms of suffering in the near future. In the far future, the cerebral organoids might be let evolving until to become authentic pieces of “human brain,” of course only in a Petri dish, but living and “sentient”: “something” that, for sure, cannot be reducible to simple “object.” As a consequence, one might pose the question of whether or not we have

to recognize some “status” to these “organoids.” It could be a legal status different from the one of mere “possessions” (or “objects”). It would be difficult, in fact, to qualify those active and “sentient” pieces of human brain, just mere “things.” At the same time, even if these organoids go so far, as to become extremely sophisticated, they would be, in any case, different from a human being. A human being, in fact, is not composed “only” of brain cells. Therefore, they should not be equated to a human body of course; either, they should not be compared to the embryos, which are able to develop into a “complete” human being (a fetus first, a baby after) and not just into a “piece of the brain.” Consequently, one cannot argue, for sure, to assign any full “legal personhood” to the living brain cells of the organoid. However, it cannot be excluded that a further debate might arise about how about legally consider these “mini-brains” and if they might be vested of some “legal subjectivity” (lower than legal personhood). That will boost, of course, the complexity of the scenario related to the boundaries of the “legal personhood” far beyond the problems posed today by the embryos.

However, the debate on the frontiers of the legal personhood does not cover the human being solely (or the human cells, like embryos or cerebral organoids).

It is far from dormant the debate whether or not “a sort of” legal personhood shall also be recognized to non-human animals, at least those who seem to have higher cognitive capabilities (and sufficient neural architecture to “feel” pain).

Under this point of view, there are philosophical doctrines that argue the opportunity to “create” a new “category” of entities, in between the “subject” (human being) and the “object” (the “possessions” or “things”): the category of “*ethical objects*.”

The formula reveals the “intermediate” nature of those entities, which are floating above the sharp distinction between mere “objects,” which does not possess any moral status, and the persons, who, of course, do possess a full moral status.

Under a certain aspect, this new formula might not be limited just to the bioethical debate. Indeed, the recognition of “moral status” to the “ethical objects” may lead the pathway to a modification of the same legal category of “legal personhood” we are familiarized with, eventually by the recognition of some forms of “legal subjectivity” (if

not the recognition of a form of proper “legal personhood”) to these “living entities.” And this category might encompass, for example, also the “brain organoids.”

All the brief considerations above – about the canons for the definition of death, at the end of life; about the uncertain status of the embryo (admittedly, not a “thing,” perhaps a “subject” but not a “legal person”) at the beginning of life; and about the status of some non-human “entities” (cerebral organoids, animals) at a specific high stage of development (sensitivity to pain, for example) – show how the evolution of life sciences opens up complex and uncertain scenarios in respect of the once much more stable legal concepts of “person,” “subject,” and “object.” The aforesaid changing contours of juridical personhood status about “living entities” have also to cope with the “parallel” debate about attributing, or excluding, some form of legal position to “non-living” entities which show some peculiar characteristics of “autonomous” and self-adaptive behavior, as the result of deep-learning algorithmic activity. Obviously, this refers to the wide realm of sophisticated Artificial Intelligence’s devices, which development is increasing rapidly. It is well known that there was a legal initiative to establish a new form of juridical personhood for robots and A.I.: a sort of “electronic personhood” (*Recommendation to the European Commission on Civil Law Rules on Robotics*, adopted by the EU Parliament on 16 February 2017 ((2015/2103(INL))). However, this initiative was rebutted by a subsequent vote of the same EU House (*Recommendations to the Commission on a civil liability regime for artificial intelligence*” on 20 October 2020 (2020/2014(INL))). As a matter of fact, the newest EU Regulation No 2024/1689 (“AI Act”) does not recognize any form of juristic personhood to AI’s devices. In Italian Law, robots and the A.I. systems, despite their eventual higher technological sophistication, and even if they possess some form of deep learning capability or autonomy (in terms of ability to self-infer new solutions for variant operational contexts), are still considered “tools” and, therefore, “legal objects” (not “subjects”).

## **5. Autonomy, Dignity, and Pursuit of Happiness as Principles of Biolaw**

The advance of life sciences and technologies during the last decades took place in a “disenchanted world,” where ideological, cultural, and ethical pluralism bloomed.

The dissolution of the authority’s principle and the sunset of common moral ground in the society have progressively determined new ways to conceive society and authority. The external authorities (such as the State, or the physicians) were no more being credited as the “sole mentors” (under a “paternalistic” point of view) of the individual “health” and “wellbeing.” What constitutes “health” or “wellbeing” of each individual – it has been affirmed – shall be decided by the same individual, according to her identity, moral preferences, and values.

As a consequence, the principle of personal autonomy became central in the juridical approach to questions regarding life sciences and technologies. Those questions, in fact, are strictly intertwined with the concept of health and psychophysical integrity. They are also so dependent to the different “life choices” (and “life projects”) made possible by the opportunities opened by the same biomedicine and biology.

The rise of the individual liberty in respect of choices regarding biology and medicine has been reinforced by the national constitutions and supranational/international charters adopted at the different levels of government. Those documents, in fact, coherently with the paradigm of the pluralistic democracy grounded on the rule of law (spread all over the West and in many cases also outside the West, since the aftermath of the II World War), do widely protect self-determination and allow the intervention of the state only under the law, solely for compelling public interests and strictly within the boundaries of proportionality and reasonability.

For example, the principle of self-autonomy (and of the informed consent) has been recognized and guaranteed by Article 6 of the UNESCO Universal Declaration on Bioethics and Human Rights (2005); by Article 3, paragraph 2, of the EU Charter of Fundamental Rights; by the Article 8 of the European Convention on Human Rights; by the Article 5 of the Convention on Human Rights and Biomedicine; by the Articles 2, 13 and 32 of the Italian Constitution, and so on. The

rule of informed consent has been rooted in U.S. since the cases of *Mohr v. Williams* [104 Minn. 261, 116 N.W. 351 (1908)] and *Schloendorff v. Society of N.Y. Hospital* [211 N.Y. 125, 105 N.E. 92 (1914)]. In China, Article 109 of the Civil Code (2020) states that the personal liberty of an individual has to be safeguarded by law. Regarding life-sciences in particular, the Chinese Civil Code adopts the principle of informed consent in medical treatments (Article 1219), in clinical trials (Article 1008), in organ donation (Article 1006).

Today, Biolaw will face tremendous challenges in safeguarding autonomy of the individual moving from the realm of bodily integrity ("*habeas corpus*") up to the "*sancta sanctorum*" of the same mental/brain integrity ("*habeas mentem*"). New bio-technologies, like brain-computer interfaces (BCI), combining also Artificial Intelligence devices, are able to establish powerful and reliable bridges between the cerebral activity *in vivo* and the outside. The OECD Recommendation on "Responsible Innovation in Neurotechnology", adopted on Dec. 11, 2019, defines "neuro-technologies" as devices and procedures used to access, monitor, analyze, evaluate, manipulate, and/or emulate the structure and functioning of the neuronal systems of natural persons. These include brain-computer interfaces, neuroimaging techniques, and neuro-stimulation devices. The opportunities they present for health and personality development, especially for people with disabilities, are immense. However, it's crucial to acknowledge that they also pose potential risks that need to be carefully addressed. This requires establishing a robust regulatory framework that aligns with the principle of the centrality of the human person and safeguards fundamental rights. These fundamental rights encompass evolved freedoms such as "cognitive freedom," which ensures that individuals maintain complete and autonomous conscious control over their mental states and cognitive functions when using those type of technologies. In the U.S., Colorado and California have enacted laws classifying "neural data" – information from the nervous system treated by a device – as "sensitive personal information". This designation subjects such data to strict standards, including consumer consent, data collection limits, and individuals' rights to access and delete data (Section 1798.140 of California Civil Code; Section 6-1-1303 of Colorado Revised Statutes). In Spain, the non-statutory (and not legally binding) Charter of Digital Rights ("*Carta de Derechos Digitales*")



establishes “neuro-rights” emphasizing personal autonomy and data security related to neural processes (Article XXVI). Chile’s constitutional reform mandates the protection of brain signals under the right to physical and psychological liberty, promoting individuals’ integrity and well-being (art. 19, 1st sect. Constitution of Chile). While, there are some sector-specific rules (such as those governing privacy, AI, medical devices, and products), that might also apply to neuro-devices aiming to protect human dignity and personal rights, a comprehensive legal framework, at international or supranational level, specifically addressing neuro-technologies “as such” is still not effective. As a matter of fact, there is a significant doctrinal and political debate at the supranational level to enshrine “neuro-rights” into legal acts. UNESCO’s Ad Hoc Group is developing a “Recommendation on the Ethics of Neurotechnology” to establish ethical and legal guidelines for developing and using neuro-technologies. This recommendation will be deliberated and adopted during the 53rd session of the General Conference in November 2025.

Besides the principle of autonomy, it is also ubiquitous in Biolaw the principle of (human) dignity.

The human dignity has had different meanings throughout history, and it would be out of the limits of these brief remarks, to plunge into the details of a so complex and multilayered philosophical, bioethical and legal concept. In the Roman era, Cicero referred the idea of dignity to differentiation and hierarchy in honor and public virtue between the individuals; on the contrary, the dignity it has been evaluated as a quality inherent to the human being, and therefore linked with the principle of equality, because of his own ontological status and therefore identical for all, in the Christian thought. Also, in the secular thought, human dignity has been conceived as a common quality of every man, starting from the Renaissance, by Pico della Mirandola, and then during the Enlightenment, by Kant, in relation to the man as a being entity endowed with conscience and reason. For Proudhon, and his economic-political thinking during the Industrial Revolution, dignity is linked to the need to ensure everyone, through appropriate social interventions, a dignified existence as free from misery, and therefore could be the base of substantive equality principle social rights.

Although there are no codified definitions of dignity in legislative texts, dignity is generally recognized as a universal, inviolable, inalienable principle of value which pertains to every human being (subject) and which constitutes the very basis, the very substance, of fundamental rights, as well as the (metaphorical) “balance” on which are weighted the fundamental rights.

In the aftermath of the II World War, the principle of dignity has been solemnly proclaimed, in legal forms at various levels, international, supranational, and constitutional.

The human dignity has been stated in the Preamble and Article 1 of the UN Universal Declaration of Human Rights; in the Articles 1 and 2 of the UNESCO Universal Declaration on Bioethics and Human Rights; in the Article 10 of the International Covenant on Civil and Political Rights; in the Article 13 of the International Covenant on Economic, Social and Cultural Rights; in the Article 1 of the Convention on Human Rights and Biomedicine; in the Preamble and Article 1 of the EU Charter of Fundamental Rights. The Italian Constitution refers to the fundamental principle of human dignity in the Article 2 and in the Article 3 where it is stated connected with social equality, and it identifies the respect for human dignity as both a limit to the freedom to conduct business, in the Article 41, and as an objective to be protected in the employment relationships, in the Article 38. In China, human dignity has been recognized as a personality right, to be protected by law against any infringement, by the Civil Code (Article 109 and Article 1002).

In Biolaw, the principle of “human dignity” has often been used to support and reinforce the principle of autonomy.

For example, in end-of-life situations, it has been argued that exercising personal autonomy in refusing a life-sustaining treatment, or in asking to receive a medical aid to die, is a way to autonomously decide when and how to leave “with dignity” her own life, a way to close autonomously an existence that, accordingly to the same individual perception, is no worthier living. Under that point of view, in Italy, the Court of Cassation has used the human dignity’s argument to support the recognition of personal freedom to choose for the refusal of life support treatment coherently with the individual’s vision of the dignity of existence in certain pathological conditions (Italian Court of Cassation No 21748/2007, followed by the Italian Council of State, No

4460/2014). The Italian Constitutional Court also nodded to the right to obtain a death deemed by the subject to be dignified in asserting the possibility of requesting the help of doctors to die more quickly after it has been decided to stop or give up a medical life-support device (Italian Constitutional Court, No 242/2019). Many of the U.S. states' statutes that have introduced physician-assisted suicide have been motivated by safeguarding the principles of autonomy and dignity of the terminally ill people.

However, there have also been cases in which the "human dignity" has been invoked as a limit to the choices that the individual alone (adult, competent) can make, following her own will and personality.

For example, the human dignity's argument has been spent on preventing adults from participating in a bloodless role-playing game, whose modalities has been considered not respectful of human dignity insofar makes the players sort of human targets (EU Court of Justice, No C-63/02, *Omega*). The same argument has been used in order to ban the exercise of the art of the circus to subjects of short stature, who performed by being thrown by the public (dwarf-tossing: French *Conseil d'État*, 27 October 1995). Indeed, this practice, although consciously and voluntarily accepted by the artist, was considered detrimental to human dignity because it reduces the man to a projectile. In Italy, prostitution has been considered harmful to human dignity, even when it is entirely the result of free choice (Italian Constitutional Court, No 141/2019), and surrogacy has been stigmatized against human dignity even if undertaken in a free manner and without any constraint or economic gain (Italian Constitutional Court, No 272/2017).

The presented examples show how the value of human dignity, which is paramount in the Biolaw (as well as in the other areas of the law), might have a twofold, ambiguous nature. On one side, human dignity emphasizes the *biographical dimension* of the individual and, therefore, her freedom (autonomy and privacy) in making choices (dignity as an "*empowerment*"); on the other side, emphasized the *ontological dimension* of the same individual, and therefore limits those choices that are perceived as *self-disqualifying* (dignity as a "*constraint*") (that amphibological character of human dignity has been pointed out recently by the Italian Constitutional Court No 135/2024).

Of course, if protecting the *inherent character* of human dignity may not result *only* in limiting the *same individual in the choices which affect uniquely the individual* (like the examples mentioned above), the same character constitutes, *a fortiori*, a limit in respect of the choices that regards *other individuals*.

In fact, whatever may be the meaning to be attributed to the formula of “human dignity” used in those documents, it is generally accepted that the “reification,” humiliation, degradation, mortification, existential discrimination (and mockery) of an individual should be regarded as wounds to dignity. Consequently, the Biolaw has the responsibility to rule the access and the usage of life sciences and technologies by an individual to avoid that this access or use determines one of the aforementioned breaches to the dignity of another individual.

Particular protection, moreover, has to be dedicated to vulnerable persons. In fact, in the mentioned above bio-legal documents (such as the Universal Declaration on Bioethics and Human Rights, or the Convention on Human Rights and Biomedicine, or the EU Charter of Fundamental Rights, or the same Italian Constitution), dignity is affirmed as a universal attribute of every human being, notwithstanding the specific health or social conditions in which is living. Therefore, human dignity shall not diminish according to any particular personal situation, such as age, illness, minority, disability, and so on. That implies an equal and full recognition and protection of human dignity even for those persons who are not able to exercise self-autonomy. The protection, respect, and care towards its weakest and vulnerable citizens are one of the state’s obligations and one of the key-point of social justice.

Furthermore, it seems to be worthy of consideration also the principle of *pursuit of happiness* even if it is not mentioned in European sources of Biolaw, because it has been, on the contrary, extensively debated in one of the very well-known reports about American Biolaw, approved by the influential American President’s Council of Bioethics: *Beyond Therapy: Biotechnology and the Pursuit of Happiness* (2003).

The pursuit of happiness constitutes – as well known – one of the inalienable rights, recognized by the American constitutionalism since its foundations.

Of course, the right to the “pursuit of happiness” goes hand-in-hand with the right of self-determination. The idea is that the “wellbeing” of the subject – “happiness” in the precise sense of satisfaction of one’s desires according to personal “*life project*” – should not be determined by any others, except the same individual (and, at the very dawn of the American Revolution, this idea was revolutionary compared to the enlightened paternalism of European sovereigns).

From this point of view, the right to the pursuit of happiness militates in favor of the individual freedom of choice whether or not to use life sciences and technologies.

There is no doubt, in fact, that the opportunities opened up by biomedicine – we may think, for example, to the *in vitro* fertilization – often realize individual life projects – such as that of parenting for people who naturally could not have children – and therefore contribute to the “happiness” (as “self-realization”) of the same individual. The right to the pursuit of happiness could also justify an unrestrictive legal regulation of human enhancement if the recourse to enhancers contributes to a better self-empowerment.

However, firstly, the present postmodern culture has sometimes exaggerated the value and goals of individual aesthetics and welfare, consequently exalting a sort of possibility of human “perfection” and hidden the more authentic truth that human nature is fragile. The pursuit of happiness that passes through the search, at all costs, for forms of hedonistic or mental perfection, therefore risks generating either inauthenticity or dissatisfaction and disappointment.

Moreover, one cannot underestimate that the consequences of personal choices regarding life sciences and technologies (as well as in other cases, of course) are not lonely (at least, not always). Other subjects might be involved in those choices.

One could take, for example, the choices about genetic manipulation on germinal lines, which – of course – have an impact over the descendants; or, one might also keep in mind the choices about the exploitation or the manipulation of biodiversity, which may also affect future generations; or, one might also refer to the capability of neurosciences and pharmaceuticals to “alter,” by enhancing or by flattering, neural correlates of the memory, which may change the

relationship of the individual with her spouse, parents, relatives, and so on.

These risks are mentioned extensively in the international bio-legal documents, such as in the UNESCO Universal Declaration on Bioethics and Human Rights (Preamble and Articles 16 and 17), or the Convention on Human Rights and Biomedicine (Preamble, and Article 13, for example).

The satisfaction of an excessive aspiration of enhancement through unregulated access to future enhancing biotechnologies (and therefore just dependent by the economic needs of the individuals, the wealthiest of whom, will take the opportunity of having the enhancers), might determine a sort of eventually “perfect” being which might threaten all the other “not-enhanced” human beings, especially those who are most vulnerable.

In those cases, the overestimating of the right to pursue happiness, using the power of life sciences and technologies, might cause harm or disadvantages.

An excess of individualism, in fact, may undermine the rights and, even, the dignity of other individuals, or may determine a deeper loosening of social ties in respect to a quick satisfaction of personal needs according to strongly individualized life plans, or may impede preservation of sufficient resources for the future generations.

## **6. The COVID-19 “stress test” and Beyond: Solidarity, Self-Responsibility and Health Literacy**

The life sciences, and their related technologies, of course, were widely involved in the COVID-19 pandemic (declared by OMS as a public health international emergency on 30 January 2020, but the first notice of a new type of coronavirus was reported by WHO China County Office on 31 December 2019).

It was, in fact, clinical biomedicine that was asked to save the lives affected by the SARS-Co-V2 virus, also through life support instruments, and experimental biomedicine that was asked to find remedies to limit the current contagion and prevent new ones.

The pandemic has determined a huge “stress test” also on the legal system, in particular on the fundamental rights in democratic countries. The protection of individual health and life, and the

sustainability of the public health service, has led to restrictions on many civil liberties (assembly, circulation, creed, enterprise, and so on). Many debates arose how to ensure the dignity for the dying persons in a condition of forced, but necessary, separation from their beloved ones to prevent further infections. Tremendous questions were posed, in terms of justice and human dignity as inherent quality of everyone, notwithstanding the age or the illness, in respect to the possibility to make “tragic choices” in selecting persons to be saved if the intensive cares would become full.

The counteract against the pandemic involved the intervention of the entire multilevel system of legal and political response: international and supranational institutions (like the WHO or the European Union) were involved in adopting scientific, or economic support, or in implementing restrictive measures in international transportation; the national governments took several decisions of “lock-down” and other health and social measures; in regional or federal states, the central government had to deal also with local governments; guidelines and protocols for physicians and nurses involved in the assistance to the hospitalized COVID-19’s patients have circulated at transnational level; compulsory vaccination has been introduced by law in some States, at least for specific categories of individuals (in Italy, Constitutional Court No 12/2022 considered the quarantine not in contrast with the article 16 of the Italian Constitution, safeguarding freedom of movement; Constitutional Court No 14-15/2023 evaluated the compulsory vaccination measures adopted by the Italian legislature as compliant with the Constitution, insofar they have been determined, at least in the identification of the pathology, they have adopted by a legislative provision, they were scientifically grounded and proportionated, they were necessary to safeguard public health and did not harm the individual sanity, the State foresaw a compensation in case of damages eventually correlated).

Some health measures against SARS-CoV-2, such as vaccination and mask use, continued to be “*recommended*” (*not compulsory*) after the peak of the pandemic’s most severe crisis. It is significant to note that, according to the Italian Act No 119/2017, other vaccinations against pathogens (seasonal flu, human papillomavirus, measles, rubella, chickenpox, mumps) are not compulsory but recommended.

Even when a vaccination is *not* imposed by law but just recommended by health authorities, the choice to be vaccinated is up to individual autonomy and is not a state obligation. This establishes a “pact of mutual solidarity” between the State and the individual (Italian Constitutional Court No 181/2023). By being immunized, the individual protects herself and contributes to the herd immunity of other people. Obeying a compulsory health measure is fulfilling a “vertical social duty” of solidarity, as the behavior is (legally) imposed by the State to protect the general welfare. Accepting to follow a recommended health measure is a “horizontal civic duty” of solidarity, as the state power does not obligate the behavior. However, it is self-responsibly accepted by the citizen to protect herself and others mutually.

During the COVID-19 outbreak, the WHO strongly outlined the risks of the so-called “infodemic,” considering it as a sort of parallel “challenge” concerning the disease itself. The neologism identifies an excessive amount (an “overabundance”) of information online or offline, some accurate and some not (non-malicious: *misinformation* or malicious: *dis-information*) during an epidemic, which makes it challenging for people to find reliable sources and guidance. This “infodemic” is not just a problem of information overload, but a severe threat to public health. It can lead to the spread of accurate and inaccurate information, creating confusion and hindering public health responses, costing, at last, human lives (i.e., without appropriate information, diagnostic tests might go unused, or immunization campaigns might not meet their targets). In the document “*Managing the COVID-19 infodemic: Promoting healthy behaviors and mitigating the harm from misinformation and disinformation*”, released on 23 September 2020, the same WHO urges the States to put into effect action plans to address the “infodemic” by increasing the offering of appropriate public health education, especially for the most vulnerable groups. From this perspective, COVID-19, as the first pandemic of the digital age in a world fully covered by extended social-media platforms, has been a significant “catalyst” for the open debate about “*health literacy*” (a term used for the first time in 1974). Broadly assumed, “health literacy” should be considered as the ability acquired by the individual to find, understand, and use information and services to make health-related decisions and actions for themselves and others.



As mentioned, “autonomy” might be considered a fundamental principle in Biolaw: yet, in order to allow the individual to enjoy her right of self-determination in health decisions, the same individual has to be “aware” – *not just merely “informed”* – of the consequences of the choice adopted for the wellness of herself but also, in a broad dimension, for the public health (as the pandemic has clearly shown). This kind of awareness could be reached if the individual has a various background and skills (cognitive, social, motivational, educational ...). It is by virtue of this “*health literacy*,” in fact, that the individual might become able, firstly, to avoid the risks of misinformation, disinformation, or rumors while navigating the vast sea of digital resources, and, secondly, to use the accurate and appropriate information received in ways which promote and maintain good health for herself and then for other members of the community.

The COVID-19, being a contagious disease, has also contributed to “*rediscover*” the intimate *relational* and *social* dimension of the individual. Everyone, in fact, was faced with the immediate consequences of her personal choices for the others. Self-protecting from the virus (by wearing masks or keeping social distancing or washing hands, or going thru vaccinations, even if they are not compulsory but recommended) became a way to protect the others, and vice versa.

Also the proactive and self-responsible behavior to remain adequately and properly informed about health individual countermeasures against COVID-19 became *not only a way* to self-protect against the illness but also to protect the others health.

This peculiar relational and social dimension of individual life, rediscovered during the time of the COVID-19 pandemic, might contribute to the *reevaluation* of the same principle of “*solidarity*,” according to which the *satisfaction of the individual rights* – i.e., in the case of a pandemic, the same, very basic, rights to life and health – should never be untied from the *individual duties and responsibilities to the benefit of the other members of the political community* – i.e., in the case of a pandemic, the duty and responsibility to act as to avoid the spread of the contagion, also by self-acquiring a proper level of *health literacy*.

This meaning of the principle of solidarity is the one stated in the Article 1 of the UN Universal Declaration of Human Rights, where it is written that “All human beings... should act towards one another

in a spirit of brotherhood” and repeated in the subsequent Article 29, where it is affirmed that: “Everyone has duties to the community in which alone the free and full development of his personality is possible.” The principle is also mentioned in the UN Declaration on the Right and Responsibility of Individuals, Groups and Organs of Society to Promote and Protect Universally Recognized Human Rights and Fundamental Freedoms (1998), and in the preamble of the International Covenant on Economic, Social and Cultural Rights. It is a principle recalled, even a little bit generally, by the Convention on Human Rights and Biomedicine (Preamble: “Wishing to remind all members of society of their rights and responsibilities”), and by the UNESCO Universal Declaration on Bioethics and Human Rights (Preamble: “Also recognizing that decisions regarding ethical issues in medicine, life sciences and associated technologies may have an impact on individuals, families, groups or communities and humankind as a whole”). The same principle is also embodied in the Italian Constitution, at the Article 2, where it is solemnly affirmed that the Italian Republic, as well as it recognizes and guarantees the fundamental *rights* of the men, as an individual, and as a component of those social groups where human personality flourishes, expects the fulfillment, by the *same individual*, of the fundamental *duties* of political, economic and social solidarity.

## 7. Conclusive notes

This essay does not seek to draw a specific conclusion but will instead provide a few final observations. The legal landscape surrounding the life sciences is in a state of constant evolution, mirroring the changes occurring within the life sciences and in society at large (see *supra*, § 2). Thus, it is only the future – albeit somewhat vaguely defined in an ever-changing world – that will offer definitive insights and unveil new possibilities.

However, to tie up the discussion, the interplay between law and the life sciences confronts a tapestry of intricate and evolving challenges, three of which might be finally highlighted here.

Firstly, there is a constant resurgence of cultural and ideological diversity at the national level, a backlash against globalization, and growing geopolitical fractures between the West and East. There is also

increasing distrust towards international organizations in health (such as the WHO) or culture (like UNESCO), which complicates efforts to establish a “global” framework of principles and rules for life sciences. Conversely, at the supranational level, the European Union has ramped up its regulatory efforts in recent years, promoting greater uniformity among the legal systems of member states across several areas of life sciences (such as clinical trials, responses to pandemic threats, medical devices, the circulation of clinical data, and the deployment of digital and AI services for both individual and public health). The EU’s growing influence in establishing regulations for technological applications in life sciences could give rise to a “*Brussels effect*,” impacting legal frameworks globally. Such a trend may play a significant role in harmonizing the legal landscape within the biosciences sector. An integrated set of principles and rules established at either the international or transnational level would facilitate the advancement of life sciences and technologies within a framework that upholds human rights and dignity. As research and technological advancements in life sciences increasingly rely on networks of public and private institutions across various countries, a more standardized regulatory environment will foster collaboration among researchers and developers, transcending national borders. Moreover, a more consistent set of regulations in biosciences and biotechnologies would deter states from creating legal frameworks that promote unfair competition in life sciences research and development, driven by geopolitical or economic motivations. However, it is also important to acknowledge that “political sovereignty” – particularly within the Western democratic model – is still represented mainly by *national* elected bodies with lawmaking powers (with the exception of very few supranational entities, like the EU, which do possess legislative chamber elected by citizens). Consequently, regulations established at the national level by political bodies that reflect the will of their constituents cannot be easily disregarded. This consideration is particularly significant in a world characterized by resurgent national identities and political divisions.

Neglecting to address this issue adequately could impose a precarious “clamp” on democratic frameworks – particularly in the West. On one side, there is the challenge for national bodies, which are accountable to the electorate, to effectively regulate life technologies

while also respecting constitutional and cultural identities. This challenge often leads to a fragmented legal landscape that struggles to manage technological advancements, which frequently have international implications. On the other side, although international and transnational governance may be preferred, the formulation of “global” rules governing life technologies faces obstacles related to political legitimacy and a shared cultural identity, hindering their successful implementation within national contexts.

As a result, both elements of “global law” and “national law” appear necessary to regulate the development of life sciences and technologies. Therefore, a foundational principle of a “*loyal cooperative relationship*” between various institutional bodies (such as courts, legislative branches, and political forums) is essential in Biolaw.

Concluding this first final remark, the intricate interplay (or “prism”) of multilevel and transnational factors, coupled with a significant national component, aptly illustrates the current and foreseeable systems of legal sources in Biolaw (see *supra*, § 3).

Secondly, neither the European Union (including its Member States) nor the United States has established a clearly defined a *new* concept of legal subjectivity, apart from legal personality, that can be applied to unborn human entities, advanced artificial intelligence systems, or certain synthetic forms of biological life, such as organoids. Nonetheless, one could argue that the question of legal “*subjectivity*” – separated from legal “*personhood*” – is a crucial issue that Biolaw must address, both on a global scale and at the national level.

It is reasonable to suggest that the resistance to the introduction of novel forms of “*electronic legal subjectivity*” (often referred to as “*e-personhood*”) stems from an anthropocentric perspective. This resistance is fueled by challenges in imputing legal relations to artificial entities, in the concerns about “*humanizing*” the AI system by giving them “*subjectivity*”, and in the several uncertainties surrounding civil liability when an AI system becomes a subject, legally responsible for torts. These factors will likely continue to hinder the development of new forms of “*legal subjectivity*” for artificial intelligence systems.

In the different context of recognizing legal personality for embryos and fetuses – essentially unborn human entities – the debate becomes intertwined with discussions surrounding the

extension or limitation of voluntary interruption of pregnancy and medically assisted procreation. Granting full legal personhood for embryos or fetuses would likely lead to more restrictive limitations on technical procedures that could potentially infringe their rights to life and development. Therefore, re-framing the legal status of the embryo or of the fetus must be balanced against the rights related to individual autonomy, parenthood, and health of the woman involved.

The depicted scenario suggests a gradual “unbundling” of the “intertwining” of natural legal personhood, dignity, and the status of human beings as a born and living entity.

A more “nuanced” spectrum must be accepted regarding different forms of legal standing: it ranges from entities that are whole legal persons (such as human beings from birth to death without any discrimination) to entities that are legal *subjects* but *not* whole *persons* (like the embryos and the fetuses, or the corpses), to entities that are legal *agents* (such as AI algorithms capable of deep learning and autonomous behaviors), and finally to entities that are merely legal objects (“*res*”).

Ending this second remark, the re-evaluation of legal personhood and the associated notions of subjectivity is likely to remain a central point of contention in Biolaw discussions throughout the coming decades of the 21st Century (see *supra*, § 3).

Thirdly, a “global law” pertaining to the life sciences must be grounded in fundamental principles of human dignity, individual autonomy, and the “pursuit of happiness.”

As previously indicated, human dignity, despite its inherent ambiguity, is firmly anchored in international law. It has been recognized as a fundamental right within the European legal framework and has been designated as a personality right in China. Furthermore, the principle of individual autonomy is acknowledged across various legal systems, including international law, U.S. constitutional and statutory law, European charters on fundamental rights, and the Chinese Civil Code (even, if following the Confucian cultural and religious heritage, the most important decisions about health and the body are taken in dialogue with the components of the family).

Principles of human dignity and autonomy are especially pertinent – today – when evaluating emerging intrusions into deeply

personal realms, such as the neuro-technology (which, along with AI, represents one of the most significant areas of legal intervention both now and in the future).

However, these established principles in Biolaw must be harmonized with the principle of “individual responsibility.” This principle applies to the exercise of rights regarding biotechnologies. It emphasizes an increased responsibility similar to that invoked in environmental law, where solidarity in using natural resources and preserving living conditions for future generations is crucial.

To put it in other terms, rooted in the cultural revolution of the Sixties, bioethics (first) and Biolaw (after) have advocated the claim to set free the individual from authoritative (paternalistic) bio-power. That is why, until today, Western bioethics and Biolaw have posed so much increased attention to the broadest effectivity possible of the rights of individual self-autonomy in choices regarding the body and healthcare. While this “liberation” is commendable – allowing for a recognition of each individual autonomy and happiness – a deformed self-autonomy and pursuit of happiness – where individuals are perceived exclusively as right-holders, without acknowledging their roles as duty-bearers – may jeopardize the social bonds that tie them to the “political community” (i.e., the “Republic” as “*res publica*”).

This means that the principles of the pursuit of happiness and autonomy should not be viewed as absolute. They require a reasonable balance and proportionality, which may necessitate legal intervention, particularly in relation to the future development of biotechnology. From this perspective, as one considers the future developments of Biolaw, at both global and national levels, it’s essential to remember that in a political community, the rights to self-determination and the pursuit of happiness should not give rise to excessive and “solipsistic” individualism.

Finishing this third remark, the 21st Century Biolaw cannot escape the research on a delicate equilibrium between the “right of autonomy” and “duty of responsibility.” (see *supra*, §§ 5 and 6).

As we look toward the horizon of our journey, it becomes that the “constitutional” dimension of Biolaw, at global and national level, encompasses a variety of noteworthy elements. These elements, which include legal interpretations, ethical considerations, and societal implications, will play a crucial role in shaping the direction and

effectiveness of Biolaw in navigating the high seas of biotechnological challenges.