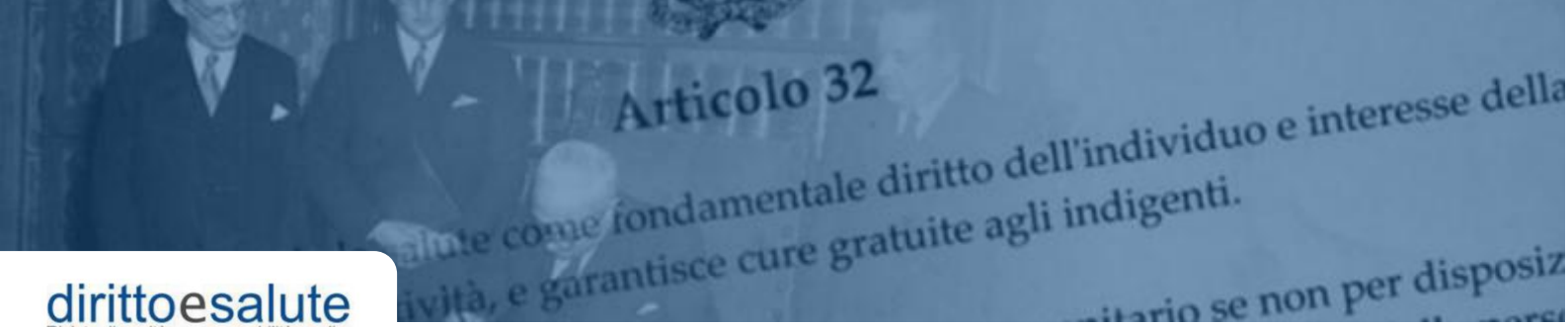

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Health for sale. Reflections on ethics, law and welfare.

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Abstract EN: The article analyses how bodies become economic resources at the intersection of ethics, biolaw and welfare. Using autonomy, beneficence, non-maleficence and justice as analytical anchors, it highlights the structural tension between unpaid donations and the marketisation of derivatives across biotech value chains. In light of the new EU SoHO Regulation (2024/1938)—which reaffirms voluntary unpaid donation and allows financially neutral compensation—the paper advances a fair-value framework: supply-chain transparency, safeguards against vulnerability/coercion, solidarity-based pricing of derivatives, national self-sufficiency plans, and social-return mechanisms. The aim is to reconcile human dignity, distributive justice and health-system sustainability — not by "pricing the body" but by equitably governing the value that flows from it.

Abstract IT: L'articolo esamina la trasformazione dei corpi in risorse economiche alla luce dell'intreccio tra etica, biodiritto e welfare. Muovendo dai principi di autonomia, beneficenza, non maleficenza e giustizia, il saggio mostra la tensione strutturale tra conferimenti gratuiti e commercializzazione dei derivati lungo la filiera biotecnologica. Alla luce del nuovo Regolamento (UE) 2024/1938 sulle SoHO, che riafferma la donazione volontaria e non retribuita e ammette compensazioni finanziariamente neutrali, si propone un framework di *fair value*: trasparenza economica, presìdi contro vulnerabilità/coercizioni, politiche dei prezzi solidaristiche e piani di autosufficienza, con meccanismi di ritorno sociale. L'obiettivo è garantire il rispetto della dignità, giustizia distributiva e sostenibilità dei sistemi sanitari, senza "dare un prezzo al corpo" ma governando equamente il valore generato.

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1. The new market for bodies.

Over the last few decades, production processes and, in some respects, reproductive processes have undergone a profound reconfiguration, largely determined by advances in biotechnology applied to health. This transformation has necessitated a conceptual revision of the notion of the commodification of biology, which has become increasingly articulated and complex. In this context, the concept of biocapital takes on particular significance.[1]

The emergence of new forms of production has given rise to an economic system based on biotechnological mobilisation and the availability of a wide range of biological resources: from genetic information to gametes, from umbilical cords to pluripotent stem cells, to cryopreserved tissues. This framework, made possible by technical progress and the dynamics of globalisation, has fuelled the rapid expansion of a multi-million-pound market populated by multiple actors (doctors, lawyers, intermediaries, pharmaceutical companies), requiring, precisely because of its scope and impact, an in-depth reflection on bio-law accompanied by targeted legislative measures.

However, this growth raises important ethical and legal questions, especially in relation to the protection of human dignity, anchored in the principles of the Oviedo Convention[2] and the Charter of Fundamental Rights of the European Union[3].

The intertwining of the exploitation and commercialisation of biological resources, the emergence of new economic interests and relentless technological innovation are testing the effectiveness of traditional biolaw instruments. There are those who believe that these instruments are gradually losing their regulatory capacity in relation to the critical issues posed by biocapital, proving inadequate to govern the growing intersection between the market and corporeality. The crucial issue concerns the governance of the relationship between bodies and the market, often marked by ambivalence and inconsistency, not least because of the difficulty of asserting the principle of individual self-determination in this area.

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[1] According to Mario Turrini's definition, biocapital represents a new form of capital generated by the translation of life itself into information or generative capacity. See M. TURRINI, *Biotecnologie, salute e lavoro clinico,* in M. TURRINI (ed.), *Biocapitale,* Ombre Corte, 2011, 9.

[2] Article 21, in fact, unequivocally states that «The human body and its parts shall not, as such, give rise to financial gain». Convention on Human Rights and Biomedicine, Art. 21, https://rm.coe.int/168007cf98 (accessed on 15/10/2025).

[3] Art. 3, CDFUE, «1. Everyone has the right to their physical and mental integrity. 2. In the field of medicine and biology, the following must be respected in particular: the free and informed consent of the person concerned, in accordance with the procedures laid down by law; the prohibition of eugenic practices, in particular those aimed at selecting persons; the prohibition of making the human body and its parts as such a source of financial gain; the prohibition of the reproductive cloning of human beings».

From a broader perspective, some of the literature has highlighted how the end of Fordism has led, since the end of the 20th century, to a post-Fordist system with more flexible, precarious and outsourced work. This transition has made previously marginal dimensions economically relevant, in particular the relational and bodily dimensions of work[4]. The twentieth century brought the production process into the body, circulating organs, blood and cell lines outside the body itself, undermining the Marxian distinction between living and inert[5]. In this sense, neoliberalism tends to dissolve the boundaries between production and reproduction, work and life, market and biological matter, recognising a growing economic value in biological and generative functions[6].

In this scenario, it becomes essential to question in depth how economic transactions involving the human body intertwine with the relevant legal framework, a framework that often reveals contradictions and structural fragilities. It is, in fact, regulatory options that shape the ways in which value is extracted from bodies in the contemporary economy. Among the most important issues—which deserve broader discussion—is the tendency of biolaw to predominantly value cognitive and intangible contributions, often to the benefit of pharmaceutical companies, private clinics, and other operators in the biotechnology supply chain, at the expense of the material and productive dimension embodied by citizens' biological contributions.

In short, the current regulatory framework allows for the collection of biological material free of charge, in line with ethical and legal principles aimed at preventing the direct commodification of the body. However, once these materials undergo valorisation processes thanks to the technical, scientific and organisational contribution of the actors in the supply chain—intermediaries, laboratories, private healthcare facilities, companies—they often re-enter the economic circuit according to commercial logic, becoming goods sold for a fee. These dynamic highlights a structural tension: the gratuitousness of the initial gesture coexists with the subsequent placing of the transformed products on the market, raising ethical and legal questions about the legitimacy of such practices and the protection of the people involved.

The sequence of free collection, industrial exploitation and commercialisation therefore calls for critical reflection on the dialectic between ethics, bioethics and regulation. The gap between the initial phase of donation, often motivated by solidarity and collective interest, and the

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[4] See B. CASALINI, *Il femminismo e le sfide del neoliberismo (Feminism and the challenges of neoliberalism),* Rome, 2018, 106; C. MARAZZI, *Il posto dei calzini. La svolta linguistica dell'economia e i suoi risvolti sulla politica (The place of socks. The linguistic shift in economics and its implications for politics),* Bellinzona, 1999. 48.

[5] M. COOPER, WALDBY, *Global Bio-Work: Bodies and New Labour,* Rome, 2015, 37

[6] M. COOPER, *Life as Surplus Value: Biotechnology and Capital in the Age of Neoliberalism,* Seattle, 2008, 31.

subsequent pricing of the product highlights the urgent need to rethink criteria of distributive justice and guarantees of individual rights in the management of biological resources.

In this debate, ethics — as an examination of the principles that guide action — and bioethics — specifically concerned with the moral implications of the life sciences—are at the centre of a multi-layered discussion that touches on the value of dignity and the balance between private interests and the common good. A crucial question concerns the legitimacy of private appropriation of biological materials and the possibility of drawing clear boundaries between lawful scientific exploitation and the violation of fundamental rights.

In this perspective, the principle of self-determination takes on decisive importance: the right of each individual to dispose of their own body and its components cannot be assessed solely from a legal point of view, but must be placed within a broader ethical horizon, capable of grasping the implications of placing value on human life. Today's biotechnologies, in fact, transform the biological into an economic object, making the boundary between the body as the holder of rights and the body as a source of value increasingly blurred.

These considerations highlight the risk that the current regulatory framework — still linked to the premises of biolaw developed before the biotechnological revolution — may prove inadequate to govern emerging processes, fuelling imbalances between those who contribute their biological heritage and those who capitalise on the economic returns. Faced with these critical issues, a renewed examination of ethical and bioethical foundations is essential in order to guide regulatory choices and ensure a balance between scientific progress, individual rights and social justice.

The issue of the exploitation of biological resources and its intertwining with biotechnology cannot be separated from the welfare state, traditionally responsible for ensuring equitable access to essential goods — including health — and to the biological resources necessary for treatment and research. As already noted, the current model presents a paradox: while harvesting often takes place free of charge, industrial processing places the product in a paid circuit, making it accessible primarily to those with greater resources. This can lead to increased inequality, with a gap between those who make parts of their bodies available and those who benefit from biotechnological innovations in a system that tends to reward private capital more than the redistribution of the value generated.

This highlights the need for a critical assessment of the relationship between bioethics and welfare: the regulation of biomedicine should aim not only to protect individual rights, but also to ensure a more equitable public management of biological resources. Ethically conscious regulation should ensure that the benefits of innovation are not solely translated into private profits, but are reinvested in healthcare welfare systems capable of redistributing the fruits of research in a fair and egalitarian manner.

2. An Interdisciplinary Reflection.

Does it make sense to talk about ethics when discussing law and welfare? The question is far from obvious, because it forces us to question the relationship between moral principles and legal and social structures, and how regulatory choices shape the distribution of resources and opportunities in the community. Ethics—from the Greek éthos—is the branch of philosophy that investigates what is right and how human beings should act in their relationships with others, seeking a balance between individual and common interests. It attributes normative status to behaviours, distinguishing between right and wrong, lawful and unlawful actions, and does not merely describe existing values: it critically examines their foundations, asking why an act is considered right or wrong and whether moral norms should be anchored to universal principles or reformulated in the light of new contexts and knowledge. Unlike morality—a historically and culturally situated set of precepts on 'what to do'—ethics investigates the 'why' and 'how' of that doing.

In the theoretical landscape, different approaches coexist: utilitarianism (or consequentialism)[7], which evaluates the correctness of an action based on its outcomes and the maximisation of collective benefit; deontology, which recognises moral duties independent of consequences[8]; and the ethics of care, which focuses on relationships, responsibility, empathy and solidarity[9]. These principles are not abstract: they translate into fields of application—from business ethics to finance, from the ethics of technology and artificial intelligence to professional and labour ethics—in which responsibility, transparency, privacy, fair pay, security and dignity are discussed[10].

Ethics is therefore an unavoidable component of the world of work and welfare, because it directly affects lives, relationships and the distribution of goods and opportunities. Welfare, understood as a set of public, employer or social measures for the well-being and protection of citizens, is intertwined with one of the cornerstones of public ethics: distributive justice, i.e. the criteria for the equitable distribution of resources—from equality to merit—and opportunities.

To clarify the relationship between ethics, bioethics, work and welfare, it should be remembered that bioethics examines the ethical, legal and social implications of life sciences and medicine: from biomedical research to genetic engineering, from biotechnology to contemporary dilemmas on self-

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[7] See J. BENTHAM, *An Introduction to the Principles of Morals and Legislation,* Mineola, 2007.

[8] See M. KORSGAARD, *Kant: Groundwork of the Metaphysics of Morals*, in M. GREGOR, and J. TIMMERMANN (trans.), Cambridge, 2012.

[9] See C.F. GILLIGAN, *In a Different Voice,* Cambridge, 1982.

[10] See, among others, and without claiming to be exhaustive: S. RACHELS, *The Elements of Moral Philosophy,* Columbus, 2023; P. SINGER, *Practical Ethics,* Cambridge, 2011; H. SIDGWICK, *The Methods of Ethics,* Indianapolis, 1981.

determination, dignity and fundamental rights. Bioethics questions, among other things, the donation and use of body parts, assisted reproduction and gamete donation, end-of-life care, clinical and pharmacological experimentation, proposing regulatory models that protect people and distribute the benefits of science and technology fairly.

This link is not theoretical: it affects the political and legislative choices that shape society. The growing intersection between the market, the body and biotechnology require ethically based regulations that guarantee fundamental rights and prevent life from becoming a commodity reserved for those who can afford it. A provocative question helps to focus on the problem: is it lawful to sell a kidney? In most countries, the answer is no, in line with the principle that the human body cannot be traded; however, there are legal systems—such as Iran—where the sale of kidneys is legal and regulated[11]. While the WHO promotes a framework based on altruistic donation, this exception shows how the regulatory framework effectively determines who sells, who buys and under what conditions: in market contexts, sellers often come from economically vulnerable groups, while buyers have greater resources, with obvious repercussions in terms of inequality[12].

There are also areas where the boundary between donation and market is more blurred. In blood and plasma donation, for example, the EU and Italy adopt voluntary and unpaid models, while in other countries — such as the United States — plasma remuneration is legal and supports a multi-billion-dollar industry. Whenever a good or service is exchanged for financial compensation, a market is created; when the object of exchange has a large-scale impact — biological tissues, blood, oocytes, surrogacy — bioethical scrutiny becomes essential. If there is a market for bodies or bodily functions, we must first establish its legitimacy and then define the moral principles that should govern it: how far can the logic of free trade go? What limits are insurmountable?

Hence the intertwining of market ethics, bioethics and biolaw: each context requires a specific analysis that brings together economic, legal and moral dimensions. Welfare also comes into play in this dynamic, because philosophers and sociologists have interpreted gratuitousness and altruism in donations (blood, tissues, organs in systems that regulate them as gifts) as the building blocks of the welfare state. Giving, in the Maussian sense, is not mere individual generosity: it is a principle of cohesion and reciprocity that forms the basis of social bonds[13]. If public health and welfare are based on this logic,

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11 The government supervises the process through organisations such as the Charity Association for the Support of Kidney Patients (CASKP) and the Charity Foundation for Special Diseases (CFSD), which operate under the control of the Ministry of Health.

12 N. SCHEPER-HUGHES, *The Global Traffic in Human Organs,* in Current Anthropology, 2000, 200.

13 M. MAUSS, *Essay on the Gift: Forms and Reasons for Exchange in Archaic Societies,* in *L'Année Sociologique*, 1925, 40–50.

the transition from free access to the commodification of biological resources raises crucial questions: what happens to solidarity? Can welfare still guarantee equity and distributive justice?

These questions remain open and show why the bioethical discourse is central not only in medicine and law, but also in public policy and models of social justice: at stake is not only individual protection, but the very form of coexistence and the stability of the solidarity pact that underpins welfare.

3. Bioethical foundations for the body market.

As mentioned, the intertwining of bioethics, biolaw and the main issues of social justice and welfare requires case-by-case assessments. The neoliberal drive to exploit biological resources can result in exploitation and damage to dignity, but the ethical outcome is not uniform: selling blood or plasma, donating an organ or surrogacy are situations that share a reference to the body, but are not morally equivalent. Hence the need to establish theoretical criteria that will guide the analysis of surrogacy, gametes and blood, justifying different outcomes depending on the case.

The most influential model internationally remains that of Beauchamp & Childress, which articulates bioethical judgement around four principles: autonomy, beneficence, non-maleficence and justice[14].

Autonomy refers to the freedom to dispose of one's own body as an expression of the principle of self-determination[15] ; in our legal system, it is supported by Articles 2 and 13 of the Constitution and Article 8 of the ECHR on respect for private and family life. Self-determination presupposes a conscious subject free from coercion and is the basis for large areas of health protection[16]. In the clinical setting, this translates into informed consent, which requires complete and comprehensible information and the effective possibility of accepting or refusing treatment[17]. At the same time, scientific

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[14] T. BEAUCHAMP, J. CHILDRESS, *Principles of Medical Ethics,* Oxford, 1979.

[15] On the principle of self-determination, see: A. GUSMAI, *Il diritto all'autodeterminazione: una libertà "perimetrata" dal sapere scientifico? (The right to self-determination: a freedom 'bounded' by scientific knowledge?),* in Dirittifondamentali.it, Issue 1, 2019; S. MANGIAMELI, *Autodeterminazione: diritto di spessore costituzionale? (Self-determination: a constitutional right?),* in C. NAVARINI (ed.) *Autonomia e Autodeterminazione. Profili Etici, Bioetici e Giuridici,* Rome, 2011, 82; L. ANTONINI, *L'autodeterminazione nel sistema dei diritti costituzionali,* in F. D'AGOSTINO (ed.), *Autodeterminazione. Un diritto di spessore costituzionale?* Milano, 2012.

[16] A.G. GRASSO, *Per un'interpretazione costituzionalmente orientata del divieto di maternità surrogata,* Milano, 2018, 159; S. MANGIAMELI, *Autodeterminazione: diritto di spessore costituzionale?*, Report presented at the IV Sublacense laboratory on The family community and end-of-life choices, 2009, 1.

[17] Article 1 of Law No. 219/2017 (entitled *'Provisions on informed consent and advance treatment provisions*), in recognising the inter-constitutional status of the right to self-determination by virtue of 'Articles 2, 13 and 32 of the Constitution and Articles 1, 2 and 3 of the Charter of Fundamental Rights of the European Union' (paragraph 1), specifies: «every

progress is reshaping the scope of choices, expanding opportunities and pushing back the boundaries of autonomy over one's own body[18], with all the related limitations[19]: in this sense, scientists are becoming 'architects' of human potential, rewriting the «script of life»[20] beyond the natural history traditionally recounted by law and religion[21].

One (liberal) line of thought argues that, as long as the interests of third parties are not harmed, everyone can pursue their own life project according to their own convictions[22]. To be genuine, however, autonomy requires authenticity (decisions that are truly one's own and not directed by others) and awareness (understanding of the consequences)[23]. Alongside this, some approaches to relational autonomy invite us to consider people's social context (class, gender, ethnicity, etc.), albeit with the caveat—raised by various critics—that autonomy should not depend more on relationships than on the person[24]. The result is a contextualised idea of autonomy: not reducible to the social, but also not intelligible without it.

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person has the right to know their health conditions and to be informed in a comprehensive, up-to-date and understandable manner about the diagnosis, prognosis, benefits and risks of the diagnostic tests and medical treatments indicated, as well as about possible alternatives and the consequences of any refusal of medical treatment and diagnostic tests or of waiving them» (trans by the author). The text even states that «they may refuse to receive all or part of the information or indicate family members or a person they trust to receive it and give consent on their behalf if the patient so wishes» (trans by the author). In this case, «the refusal or waiver of information and any indication of a representative shall be recorded in the medical record and in the electronic health file» (paragraph 3). Awareness of this principle and its importance have led to DATs being understood as the logical outcome of informed consent.

[18] A. GUSMAI, *The right to self-determination: a freedom 'bounded' by scientific knowledge?,* in Dirittifondamentali.it, 1, 2019, 5

[19] There are several limits imposed on the right to dispose of one's own body. These include the prohibition of organ trading, M.J. RADIN, *Contested Commodities: The Trouble with Trade in Sex, Children, Body Parts, and Other Things,* Cambridge, 1996; extreme bodily modifications, J. HABERMAS, *The Future of Human Nature,* Cambridge, 2003; and the possibility of experimenting on oneself, H. JONAS, *The Imperative of Responsibility: In Search of an Ethics for the Technological Age,* Chicago, 1979

[20] For further information on 'natural history' before the advent of biology, see M. FOUCAULT, *The Order of Things: An Archaeology of the Human Sciences,* Milan, 1967, 143 ff.

[21] Z. BAUMAN, *Mortality, Immortality and Other Life Strategies,* Bologna, 2012, 124 ff., recalling how in the pre-modern phase (before the emergence of legal positivism) it was religion that constructed the meaning of the concept of human life and, consequently, influenced the very content of the rights of freedom (including, of course, the right to self-determination).

[22] See H. JACKSON, *Regulating Reproduction: Law, Technology and Autonomy,* Oxford, 2001, 2. Autonomy is also defined as 'the prerogative of the individual to live her own life, in accordance with her own values and desires: to live by her own lights'.

[23] E. NELSON, *Law, Policy and Reproductive Autonomy,* Oxford, 2013, 12.

[24] For an overview of theories opposed to the idea that informed consent can be equated with the principle of autonomy, see S. DODDS, *Choice and control in feminist bioethics*, in C. MACKENZIE AND N. STOLJAR (eds), *Relational Autonomy: Feminist Perspective on Autonomy, Agency and the Social Self,* Oxford, 2000, 213.

At the same time, other authors argue that this understanding of the principle of autonomy has its roots in liberalism and, while on the one hand it requires the state not to interfere with individuals' free decisions, on the other hand it requires the state to take action to enable all individuals to make those decisions freely and fairly. Underlying this concept is the idea that, in order to truly guarantee autonomy of choice, the state must intervene to limit external interference in decision-making.

The state, therefore, has the task of «levelling the playing field»[25] within which the decision is made in order to truly ensure autonomy of choice.

For some[26], autonomy is always influenced by social factors, race, gender, class, etc., but according to others, if interpreted in this way, the concept of autonomy would tend more towards the concept of relationship than of person, implying that if an individual falls within certain types of relationships, then they can be considered truly autonomous, otherwise their autonomy would be inexorably undermined[27].

On the one hand, some critical currents of liberalism propose a more restricted and minimal notion of autonomy; on the other hand, a broader and more comprehensive view of reproductive autonomy is considered by many to be more realistic and preferable from a normative point of view[28]. At the same time, numerous feminist theories observe that, in many concrete situations, women's decision-making capacity is severely restricted, if not entirely absent[29]. This comparison reveals a concept of autonomy that is both gradual and contextual: not based solely on the social dimension, but necessarily attentive to the way in which society affects individual choices[30]. The protection of self-determination also involves safeguarding the dignity of the person — even with regard to potentially self-harming choices — with specific attention to vulnerable individuals.

For a decision to be truly free, information must be clear and complete, and external influences must be minimised as much as possible. The protection of self-determination always implies the safeguarding of dignity — even with regard to self-harming choices — with particular attention to vulnerable

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[25] D.E. ROBERTS, *Killing the Black Body: Race, Reproduction, and the Meaning of Liberty,* New York, 1997, 150-201, 23.

[26] C. MACKENZIE, N. STOLJAR, *Introduction: Autonomy Reconfigured* in C. MACKENZIE, N. STOLJAR (eds), *Relational Autonomy: Feminist Perspectives on Autonomy, Agency and the Social Self*, New York, 2000, 4.

[27] E. NELSON, *op. cit*. 23.

[28] H. JACKSON, *Regulating Reproduction: Law, Technology and Autonomy,* Oxford, 2001, 293.

[29] Some feminist theories argue that even consenting to infertility treatments may, in some contexts, carry a risk of social stigma due to particular pressure to become a parent. See J.C. CALLAHAN, D. E. ROBERTS, A *Feminist Social Justice Approach to Reproduction-assisting Technologies: A Case Study on the Limits of Libertal Theory,* in *Ky LJ,* 84, 1997, 1197-1227.

[30] *Ibidem.*

individuals. For a choice to be truly free, complete and comprehensible information is required, and external pressures must be minimised.

The principle of beneficence expresses the moral duty to act in the patient's best interests and is divided into two parts. On the one hand, there is positive beneficence, which requires promoting well-being and pursuing the best outcome for the person; on the other hand, there is the dimension of utility, which requires choosing the intervention that maximises benefits in relation to costs. The latter also includes prevention and, where possible, the removal of harm, acting as an operational extension of beneficence and allowing for a balanced risk-benefit assessment in clinical decisions. This gives rise to rules such as the protection of the rights of others, the prevention of potential harm, the elimination of harmful conditions, support for people with disabilities and the duty to provide assistance.

Alongside beneficence, the principle of non-maleficence (the well-known *primum non nocere*) prohibits causing harm. In biomedicine, harm is not only physical: it can be psychological, social or damaging to dignity. For this reason, the principle supports practical prohibitions against killing, inflicting pain or suffering, compromising physical or cognitive abilities, humiliating individuals and depriving them of goods essential to their well-being. Together, beneficence and non-maleficence guide scientific and technological innovations towards the common good, excluding paths that harm those involved.

When progress broadens the range of choices, this expansion must take place with respect for already acquired rights: the extension of individual freedoms cannot result in violations against third parties. Consequently, a personal decision is legitimate only if it is beneficial to those concerned and not harmful to others.

The principle of justice requires that healthcare resources be allocated fairly and proportionally, ensuring that everyone has access to the highest level of care realistically available, avoiding discrimination and unjustified inequalities[31]. Philosophically, justice has been interpreted in several traditions: utilitarianism[32] aims to maximise overall well-being; egalitarianism advocates equal distribution except in reasonable circumstances. Rawls proposes justice as fairness: behind the veil of ignorance, only inequalities that improve the condition of the most disadvantaged are acceptable[33]. From a global perspective, Amartya Sen shifts the focus from resources to capabilities,

[31] N. DANIELS, *Just Health,* Cambridge, 2008, 35.
[32] J. BENTHAM, *An Introduction to the Principles of Morals and Legislation,* London, 1789, 92; J.S. MILL, *Utilitarianism,* in *Fraser's Magazine,* 1861, 27.
[33] J. RAWLS, A *Theory of Justice,* Cambridge, 1979, 65.

i.e. the actual opportunities to access health and well-being: justice is also measured in terms of real possibilities[34].

However, the general principles of bioethics should not be considered absolute, but rather 'penultimate principles' or *'prima* facie' principles[35] , until they conflict with other principles, forcing a priority assessment of the values to be protected. For this very reason, Article 26 of *the Universal Declaration on Bioethics and Human Rights,* adopted by UNESCO on 19 October 2005, emphasises that bioethical principles must be considered complementary and interdependent, and that each principle must be interpreted in the context of the others, according to criteria of proportionality and appropriateness to the circumstances[36].

This perspective highlights that justice in the field of bioethics cannot be limited to a rigid and uniform criterion of resource distribution, but must take into account the complexity of concrete situations, the social and economic context, and the actual conditions of individuals.

4. The SoHO market: between intangible/cognitive and material/productive contributions.

For some time now, various markets have developed for body parts that can be separated from the body itself and sold, sometimes free of charge, sometimes for a fee.

On this point, the new *Regulation on standards of quality and safety for substances of human origin intended for human application,* which was published in the Official Journal of the EU in June 2024 and will apply from 7 August 2027, is of fundamental importance.

The regulation aims to regulate all stages of the donation of substances of human origin from the moment of donation, preservation, storage, distribution and application to humans, in order to increase safety, efficacy and protection standards for all parties involved.

The recitals of the regulation set out some essential principles underlying our reasoning

Article 3 of the Charter prohibits making the human body and its parts as such a source of financial gain. The use of financial incentives for SoHO donations can have an impact on the quality and safety of SoHO, posing risks to the health of both SoHO donors and recipients and therefore to the protection of human health. Without affecting the responsibilities of the Member States for the definition of their health policy, and for the organisation and delivery of health services and medical care, SoHO donation should be voluntary and unpaid, and be founded on the principles of altruism of the SoHO

[34] A. SEN, *The Idea of Justice,* Cambridge, 2009, 253.
[35] W.D. ROSS, *The Right and the Good,* Oxford, 1930, 19–36.
[36] UNESCO, Universal Declaration on Bioethics and Human Rights, 2005, art. 26.

donor and solidarity between donor and recipient. Such solidarity should be built from the local and regional levels up to the national and Union levels, aiming for self-sufficiency of critical SoHO, and spreading the responsibility for donation evenly across the Union population to the extent possible. Voluntary and unpaid SoHO donation contributes to the respect for human dignity and to protecting the most vulnerable persons in society. It also contributes to high safety standards for SoHO and therefore to the protection of human health, increasing public trust in donation systems.[37]

After affirming the essential principle of the free transfer of substances of human origin and the need for there to be no financial incentives for donors in order to increase the quality and safety of the donation process, the regulation seeks to provide criteria for distinguishing between financial compensation that may or may not constitute an incentive that could influence the donor's freedom of choice and, consequently, their autonomy.

It is recognised, including by the Council of Europe Committee on Bioethics [...] that while financial gain should be avoided, compensation should be able to be acceptable to prevent SoHO donors being financially disadvantaged by their donation. Therefore, compensation to remove any such risk is deemed appropriate as long as it endeavours to guarantee financial neutrality and does not result in a financial gain for the SoHO donor or constitute an incentive that would cause a SoHO donor to not disclose relevant aspects of their medical or behavioural history or to donate in any way that could pose risks to their own health and to that of prospective recipients, in particular by donating more frequently than is allowed. It should be possible for compensation to consist of the reimbursement of expenses incurred in connection with SoHO donation or of making good of any losses, preferably based on quantifiable criteria, associated with the donation of SoHO. Whatever the form of compensation, including through financial and non-financial means, compensation schemes should not result in competition between SoHO entities for SoHO donors, including cross-border competition and in particular between SoHO entities collecting SoHO for different purposes, such as the manufacture of medicinal products versus human application as a SoHO preparation. The setting of an upper limit for compensation at national level and the application of compensation that is financially neutral for the SoHO donor have the effect of removing any incentive for SoHO donors to donate to one SoHO entity rather than another, significantly mitigating the risk that compensation differences

[37] Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC, par. (57). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1938 (last accessed on 10/10/2025).

might result in competition between SoHO entities, in particular between public and private sectors[38].

At EU level, there is a general ban on trade in tissues, blood and cells: these materials can therefore only be donated free of charge, for altruistic reasons.

The issue of compensation for SoHOs raises ethical and legal questions similar to those that have arisen in relation to surrogacy. In many jurisdictions that only allow reimbursement of expenses, egg donation risks becoming, in effect, a financial incentive, with sums ranging from approximately £700 to £1,300; where sale is legal (e.g. the United States and Canada), compensation can be as high as $50,000.

The different levels of invasiveness must also be considered: female donation involves hormonal stimulation, repeated ultrasound monitoring and surgical extraction under anaesthesia, factors that explain the higher compensation compared to male gamete donation.

Despite the risks and critical issues, the global market for medically assisted reproduction is estimated to be worth around $30 billion in 2023, with projections of growth to $50 billion by 2030.

In Italy, Law 40/2004 originally prohibited heterologous ART, but following Constitutional Court ruling 162/2014, access was granted to couples who 'have been diagnosed with a condition that causes absolute and irreversible sterility or infertility'[39]. However, Italian clinics, which do not recognise compensation for donors , purchase up to 98% of gametes from abroad and offer assisted fertilisation services for a fee, creating a market distortion where the supplier of reproductive material cannot benefit from any financial compensation, unlike intermediaries and holders of intangible/cognitive value.

A similar argument applies to blood donation.

In the European Union, donation must be free and based on altruistic motives; nevertheless, in some countries (Germany, Austria, the Czech Republic, Hungary), indirect benefits—such as vouchers or shopping vouchers—are provided to encourage participation, and these are the only

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[38] *Ibidem*, par (58).

[39] In its subsequent ruling no. 162 of 2014, the Italian Constitutional Court declared the ban on heterologous fertilisation (contemplated in Article 4, paragraph 3, of Law no. 40 of 2004) to be unlawful, on the grounds that it conflicted with the fundamental freedom of self-determination of the individual (referred to in Articles 2, 3 and 31 of the Constitution), which includes, among other things, the choice to become parents and start a family, a right that it would be unreasonable not to recognise for infertile couples (given that scientific progress now makes it possible to satisfy this right). The lifting of this ban was also justified by the protection of the right to mental and physical health (provided for in Article 32 of the Constitution), which would not have been guaranteed if psychological suffering had been caused to those couples who would have been excluded from recourse to a technique which, admitted in other countries, like homologous fertilisation, is primarily aimed at resolving reproductive problems caused by an irreversible pathological state of infertility.

European contexts in which the supply of blood and plasma exceeds demand. In contrast, plasma donations are remunerated in the United States, fuelling a market with an annual turnover far greater than that of assisted reproduction.

Europe has a deficit of around 35% between the need for and availability of blood/plasma, which are crucial for life-saving therapies and *plasma-derived medicinal products* (PDMPs). As a result, European blood banks purchase supplies from the US and Canada, where plasma collection is remunerated. This creates a paradox: while European citizens are prohibited from selling, the healthcare system imports from markets where selling is legal.

In addition, states and citizens pay for drugs derived from donated plasma—generating profits for the industry—without donors receiving any financial compensation for their contribution. Faced with increasing demand, ethical questions are resurfacing: is it acceptable to allow the sale of blood and gametes? And if the ban aims to prevent the commodification of the body, why does the system allow the sale of derivatives but not the original substance?

This asymmetry highlights broader tensions between bioethical principles, market logic and global health needs.

The issue mentioned above therefore returns with force. Western legal systems seem to move along two axes: on the one hand, the protection of the dignity and integrity of the body; on the other, the distinction between material/biological and immaterial/cognitive participation in biotechnological progress[40]. This distinction emerged with particular clarity when life was progressively translated into information, a process made possible as early as 1994 with the adoption of the TRIPs Agreement (Trade-Related Aspects of Intellectual Property Rights), promoted by the WTO at the instigation of large US pharmaceutical companies. While the stated intention was to protect scientific innovation in the health sector, the actual outcome was the creation of patent monopolies in the biotechnology field, with the effect of hindering the production of low-cost generic drugs in developing countries and, more generally, consolidating the supremacy of the most economically advanced countries[41].

The regulatory framework has progressively rewarded intangible/cognitive contributions—such as patents on genes and cell lines—benefiting universities, research centres and pharmaceutical companies, while the material/productive contribution represented by donors' bodies has remained in the shadows. Although in Europe the collection of biological materials is based on voluntariness, gratuitousness and anonymity, and therefore on altruism and solidarity between donor and recipient, this only apparent gratuitousness flows into a global economic circuit: biological resources

[40] E. CAPULLI, *Gestazione per altri: corpi riproduttivi tra biocapitale e biodiritto,* in *Biolaw Journal,* 1, 2021.
[41] V. SHIVA, *The World Under Patent,* Milan, 2002, 7.

provided without compensation are transformed and patented by the bioindustry and reintroduced onto the market as commercial products. In this way, the bodies of donors feed a constantly expanding pharmaceutical-biotechnology sector, in which individuals are first expropriated of their contribution and then reintroduced as consumers of the derivatives that result from it[42].

A similar trend concerns the circulation of oocytes which, although clearly moving within commercial dynamics, remains outside the radar of ordinary economic analyses of life sciences, thus maintaining an ambiguous legal status. In Italy, the ban on any financial compensation means that around 98% of the oocytes used come from abroad, mainly from Spain[43]. The case of the Emilia-Romagna region is emblematic, as it has banned the purchase of oocytes from foreign banks, recognising €2,000–2,500 per oocyte, a figure attributed to transport and clinical tests necessary for therapeutic use.

These data show how the prohibition on profiting from the human body is often fraught with contradictions. The issue of commodification—i.e., the treatment of the body and its parts as transferable goods—remains open both at the regulatory and political levels and at the theoretical level, which questions the concepts of property and personhood. The body-market relationship therefore requires a critical analysis capable of overcoming the traditional Marxian distinction between inanimate capital and living labour, highlighting how, today, value tends to be attributed above all to the immaterial/cognitive component, to the detriment of the material/biological one.

6. Conclusions.

In his book *The Gift Relationship: From Human Blood to Social* Policy[44] , Richard Titmuss highlights the close link between the welfare state and the ethics of gift-giving, arguing that the structure of public institutions can facilitate or inhibit altruistic behaviour. Starting from the idea that human beings are not naturally inclined to give, Titmuss clearly separates the social and economic spheres and warns that replacing the gift regime with a market regime leads to the progressive commercialisation of moral values, transforming acts of solidarity into simple transactions and, in so doing, affecting the stability of welfare.

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[42] S. ZULLO, *Body and property rights: critical issues and limits in the balance between individual and collective interests,* in *Revista de Bioética y Derecho,* 42, 2018, 156.

[43] Ministry of Health, Report of the Minister of Health to Parliament on the state of implementation of the law containing provisions on medically assisted procreation (Law No. 40 of 19 February 2004, Article 15) 2019, 15, Available at: http://www.salute.gov.it/imgs/C_17_pubblicazioni_2866_allegato.pdf (last accessed on 10/10/2025).

[44] R. TITMUSS, *The Gift Relationship. From Human Blood to Social Policy,* New York, 1970.

Applied to blood, his thesis is that the existence of a market distorts its meaning: if blood is given a price, even those who donate for free end up conceiving their gesture in monetary terms ('I did not donate life, I gave up an equivalent in money'). A key argument concerns the risk of exploitation: in the United States, most blood comes from economically vulnerable people, with a flow 'from the poor to the rich'. However, it is argued that banning remuneration could worsen the conditions of potential donors without actually eliminating exploitation. Kathleen McLaughlin[45] also takes a critical view, arguing that a portion of global medicine is based on the assumption that some Americans cannot count on a stable income and fill the economic gaps by selling blood components, while the long-term effects of frequent blood draws remain uncertain.

For Titmuss, donation is fundamental to a just society, but once institutionalised by law, it risks losing its moral authenticity and becoming an obligation rather than a free choice. In his view, the coexistence of donation and the market leads to the prevalence of commercial logic: even the 'altruistic' donor acts with an awareness of the economic value of the commodity. This view has been criticised for its clear-cut dualism (market = devoid of moral value; donation = morally elevated): in reality, there are grey areas, institutional hybrids and intermediate arrangements that do not fit into this dichotomy[46].

John Harris adds another perspective: a well-designed welfare system should focus primarily on altruism to meet social needs, but it must also provide regulatory tools to ensure the distribution of resources when altruism is not enough[47]. This leads to the final questions: can taxation and redistribution be seen as a modern form of gift-giving, or does state regulation undermine altruism, transforming it into coercive practice? And again: if the relationships between biocapital, biolabor and the market risk undermining fundamental rights, can welfare be the space in which biolaw reconciles the interests at stake?

The debate remains open and highlights the tension between equity, the market and public morality, calling into question the relationship between solidarity and institutions. In this perspective, the ethical foundations of biolaw are crucial in guiding legislators towards a balance between the trend towards the commercialisation of substances of human origin—driven by the valorisation of intangible/cognitive contributions at the expense of material/biological ones—and the need to defend the dignity of the most

[45] K. MCLAUGHLIN, *Blood Money: The Story of Life, Death, and Profit Inside America's Blood Industry,* New York, 2023.
[46] P. SILVESTRI, S. AKESTING, *An Institutional Economics of Gift?,* in *Journal of Economic Issues,* 2021, 55, 4, 954-976.
[47] D. HARRIS, *Justifying State Welfare: The New Right versus the Old Left,* Hoboken, 1987, 73.

vulnerable people, relying on voluntary donation. The welfare state is therefore called upon to play a central role in addressing the challenges posed by biotechnology: lawyers and policy makers must adopt an interdisciplinary approach, capable of integrating regulatory, ethical and scientific aspects, so as to ensure a system that is fair, sustainable and respectful of human dignity.

Taken together, contemporary bio-economies expose a structural tension between voluntary, unpaid contributions of human biological materials and the marketisation of their derivatives along increasingly complex value chains. Ethical analysis (autonomy, beneficence, non-maleficence, justice) and positive law point in the same direction: preserving human dignity and avoiding commodification as such requires not withdrawal from innovation but a different mode of governance.

The new EU SoHO Regulation (2024/1938) provides the legal anchor: it reaffirms voluntary non-remunerated donation while allowing financially neutral compensation for costs and losses, and it strengthens traceability and public oversight. To make these principles credible in practice, systems should move beyond a prohibition-only stance and articulate a fair-value governance for SoHO — combining supply-chain transparency (costs, mark-ups, public contributions), neutral compensation schemes that recognise donors' burdens without creating gain or undue inducement (including non-monetary supports), solidarity-based pricing/procurement for derivatives consistent with the altruistic origin of inputs, and safeguards against vulnerability and coercion (ethics review, demographic monitoring, independent audits). Complementing these, national self-sufficiency plans and social-return mechanisms — e.g., earmarking a share of IP- or price-based revenues to public health funds — can align private incentives with public purposes.

Framed this way, the governance of SoHO does not "price the body"; it governs the value that flows from it in transparent, proportionate and just ways. The result is a principled reconciliation: human dignity and individual autonomy are protected ex ante; beneficence and non-maleficence steer innovation toward patient and public benefit; and distributive justice is pursued through access and affordability policies that keep essential therapies within reach. This, ultimately, is the task of a welfare-oriented biolaw: not to halt the bio-economy, but to civilise it — so that biomedical progress strengthens, rather than erodes, the ethical foundations of our health systems.

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