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Consumer Protection and Cryonics

Camilla Della Giustina

University of Aberdeen, Avvocato (Rome); "specialist lawyer" in IT, digital communication and data protection JD; PhD; Student member Ciarb; vice-president Freight Leaders Council Young UK

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Abstract

Human cryopreservation is an emerging practice involving the storage of bodies or body parts at ultra-low temperatures. This practice raises profound legal and conceptual questions about personhood, contractual identity, and medical categorization. A vital element is to understand the legal status of the cryopreserved individual, i.e., whether they are best understood as a patient or consumer. The question arises because, often, cryonics organisations refer to preserved individuals as "patients," yet also use terms like "member" or "client," reflecting a semantic ambiguity with significant legal implications. This paper argues that a critical distinction must be drawn between the person who signs the cryopreservation agreement and the individual under nitrogen. The former is engaged in a commercial transaction; therefore, he/she may be classified as a consumer under contract and consumer protection law. The latter seems to better fit into the patient category.

***Corresponding author:** Dr. Camilla Della Giustina, University of Aberdeen, UK.

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An Introduction to the Cryo-Debate

The scientific origin of cryonics dates to the 19th Century, a time where scientists became aware of their ability to liquify gases at extremely low temperatures; thus, at the beginning, cryogenics was simply a technique for liquefying gases. Its applications led to the discovery of superconductivity in addition to the development of liquid hydrogen [1].

It was not before the 20th Century that cryogenic cooling was researched for medical purposes. More precisely, during the so-called Spanish Flu Pandemic, it became a necessity to find a method for storing blood, cells, and even organs of individuals for future implantation [2].

The cryopreservation practice has a problematic consequence, namely biological decay of living structures and biochemical molecules, since the formation of intercellular and extracellular ice crystals damages the tissues.

To prevent these damages, the solution is to cool the living cells in a gradual way, and in the presence of cryoprotective agents. The latter regulates the formation of ice crystals to prevent cryoinjury of the cells. From a medical perspective, cryonics is the storage and freezing of an 'unmanned' human body, in the hope, through technology development, of resurrecting it, if it were possible. It is quintessential that cryonic procedure begins immediately after 'death' or, better, in between life and death, to prevent cell decay [3]. At the beginning of the process, the blood is removed from the body and replaced with an anti-freezing fluid to prevent the crystallisation of blood and any consequent cryoinjury. The main idea is that, after death, the information stored in a human brain is left unharmed: this will be true only if the brain cell structure is preserved carefully. In other words, a dormant brain should be maintained, besides, with an appropriate stimulation, memories and personality of the individual may be reactivated [4].

Some scholars tend to distinguish between cryonics and cryo-conservation: the former is a particular application of the latter; cryo-conservation is the process of freezing human cells, such as sperm, blood, and tissues. By contrast, cryonics is the practice that involves the preservation of entire human beings and animals at very low temperatures. Nevertheless, often the two words are used synonymously. Another reference, from a terminological perspective, is hibernation: a state of inactivity, metabolic depression, and hypothermia characterised by a low body temperature, breathing frequency, slow heart rate, and low metabolic activity [5-6].

The research question of this paper is whether the individual, who signed an agreement to be preserved in liquid nitrogen either their entire body or their head (the brain), may be properly defined as a patient or consumer. From a different point of observation, such a research question should be summarised as follows: patient or consumer, this is the dilemma. In paraphrasing Hamlet's monologue, the conundrum is to understand if an individual, in entering a contract with one of the cry conservation companies, may be categorised as either a patient or a consumer. Potentially, a prospective solution is drawing a demarcation line between two different moments: when the contract has been signed but not executed, and when the contract is going to be performed because the individual is under nitrogen.

Once the purpose of this research paper has been clarified, a further element is the methodology adopted in answering this research question. The latter is based, fundamentally, on literature review: this research work kick-starts from the monograph "The Law of Cryonics: A Legal, Philosophical, and Financial Analysis", where, for the first time, the notion of cryo-patient appears [7].

To investigate this matter, first of all, it is important to recall the evolution of the notion of a patient, according to a comparative analysis; this signifies analysing the European Union perspective. The topic under spotlight is whether, in the contemporary pharmaceutical market, affected by technological development, it is more appropriate to speak about the consumer or the patient. Thus, the analysis is, per se, of an international magnitude, with strong references to the European Union regulation: this approach permits explaining the "patient"/ "consumer" dichotomy. The subsequent step consists of applying all these considerations to human cry conservation.

From the European Union standpoint, there is an intersection between the categories of consumer and patient. The key legal foundations are the Unfair Commercial Practices Directive (UCPD), the Unfair Contract Terms Directive (UCTD), and the Product Liability Directive (PLD). The former is aimed at protecting consumers in vulnerable positions, i.e., those receiving healthcare or medical products. The second covers harms caused by defective products, including medical devices and pharmaceuticals, placing the consumer in a quasi-patient role. The consumer's rights to safety and information have been reinforced by the Court of Justice of the European Union [8-11].

For example, in Tee Kanne, the Court ruled that misleading health-related labelling could violate consumer rights, even if the ingredients list is accurate. Further, in Neptune Distribution, the Court emphasised the need for accurate sodium content labelling in mineral water, reinforcing the consumer's right to health-relevant information. More recent Directives

reinforced such intersection; the reference goes to the Medical Devices Regulation (MDR) and General Product Safety Directive. These Directives define users of medical products as consumers with enhanced protection due to their vulnerability and the New Product Liability Directive. In essence, the EU legal framework is aimed at ensuring that consumers of health-related products are treated with the same care and transparency as patients, especially in cross-border healthcare contexts [12-16].

To complete the legal scenario, the Medical Devices Regulation is becoming increasingly relevant: although it is not new, this regulation continues to be pivotal in shaping consumers as patients, especially in the context of product safety, post-market surveillance, and clinical evaluation of medical devices. All the mentioned legal acts, collectively, reinforce the dual identity of the consumer as a patient, especially in contexts involving health-related products, medical technologies, and digital health tools [17].

In the described scenario, a clarification is vital: while the analysis is in between the common law of the two main countries (the British and the American) and European Union law, the perspective regulation (now missing) would be a global one. The common law role relies primarily on two main reasons. The first one is that cryonics companies are based in the US, Russia, and Australia; the only contract available is in the English language, and it is the contract adopted by Alcor Life Extension, an American company. The second one alludes to case laws: all the judgments entered so far by Courts are either US or UK Court decisions. The comparison with the European Union legal system is quintessential for two main considerations. To commence, consumer regulation is, fundamentally, European Union regulation; further, a good number of European citizens have just signed cryonics contracts [18].

The proposed analysis is based on a "law research experiment", such as how different legal systems might handle the same topic, i.e., the legal status of the individual who signed a cryonics contract and is under liquid nitrogen. The impression is that, as far as cryoconservation is concerned, the role of the law shall be necessarily a global one. The global law on cryonics will be a regulation going beyond the border, aimed at preventing both cryo-business shopping and cryo-forum shopping. This signifies avoiding a possible rush of cryopatients towards Countries where cryonics is lawful, without any clear boundaries of legality. Incidentally, this seems not to be the case in British Columbia, where, currently, cryonics is totally prohibited [19].

Individual in the Health Care Market: Looking at an Appropriate Definition

It is quite common to define a "consumer" individual who is willing to have access to the cryonics market. Each of these individuals signs a contract with a cryonics company, pays an annual membership and arranges for the eventual lump-sum payment suitable to cover the costs of preserving and storing their body [20]. This definition is shared across the world: from the United States to Australia. According to this approach, signing a cryoconservation contract implies a choice by the consumer: the latter exercises their personal dignity. Further, the payment for cryoconservation does not indicate that the consumer lacks capacity and/or is under undue influence. More precisely, cryonics organisations are under a duty to alert consumers that reanimation cannot be guaranteed [21].

This research paper advances a further perspective: the importance of distinguishing, in addition to the consumer/ patient, also between a living individual who signed the cryonics contract and the individual under nitrogen liquid. The first one might be defined as a consumer, the second one as a patient; therefore, the cryo-consumer and cryo-patient categories.

Traditionally, when an individual needs the assistance of a healthcare professional are described as a patient. This definition is affected by the paternalistic approach and emphasizes a passive position, often reminiscent of an image of suffering and of an unequal relationship. By contrast, some sociopolitical factors – among others, commodification of healthcare as well as the shift from paternalistic approach to person-centred model – have promoted a different term instead of patient, such as consumer, client, customer, or service user. The underlying idea of all these terms is empowering the greater inequality between participants in personal healthcare decision-making [22-23].

A further element responsible for this change is how we approach the relations between the individual and

healthcare staff. For example, Paul Ramsey described patients as persons: not the subject of medical treatment but, more precisely, living and breathing creatures with values, goals, and purposes. In addition, according to the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the emphasis is on respect for persons [24-25].

Yet, in the aftermath of the National Commission's Belmont Report, written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral research, the notion of "respect for persons" has become "autonomy": the latter is a concept that encapsulates rights and claims upon others. Further, autonomy was read as freedom and liberty; hence, the aim is to support an individual's rights to refuse medical treatment or prevent interference from others. In essence, autonomy alludes to the right to control and to decide about medical treatment. Thus, patient autonomy, when it is unlimited, opens the door to health commercialism [26-28].

More recently, the difference between patient and consumer has been highlighted by the UK Supreme Court in the famous case Montgomery v Lanarkshire Health Board (Montgomery). Lords Kerr and Reed drew attention to the increasing tendency to regard patients as holders of rights and as 'consumers exercising choices. As a result of this trend, the caveat emptor principle should apply to them [29].

It is worth highlighting that the UK Supreme Court draws an analogy between patient and consumer as regards informed consent. The conclusion that arises from 'Montgomery' is that the doctrine of informed consent is aimed at boosting patient autonomy by equipping patients with the information they need to exercise freedom of choice over the medical treatment they receive. Nevertheless, the main issue is that medical decisions are often unfamiliar and complex; at the same time, the duty of the doctors is to redress imbalances of knowledge and power in the doctor-patient relationship. The metaphor encapsulated in 'Montgomery' is aimed at stressing the importance of patients' rights to make informed choices on their medical treatment [31].

The Patient-Consumer Protection in the European Union Law

The main research question focuses on the interaction and the merging between the concepts of consumer and patient. When examining this issue through the lens of the European Union, it appears that the EU promotes a process of consumerisation. In the health sector, this occurs due to increased availability of medicines and therapies driven by the disappearance of boundaries between therapeutic health care and non-therapeutic health care [32].

The original rationale stems from the European Union's market-oriented approach, which increasingly shapes the regulation of healthcare products and services. More in depth, EU law has gradually shifted European societies away from principles rooted in solidarity and social citizenship, promoting a framework grounded in market logic and consumerism [33]. This transformation has inverted the traditional relationship between society and the market: rather than the economy serving social needs, social relationships are now embedded within, and often subordinated to, the economic system. Consequently, social interactions are increasingly mediated through contractual arrangements affected by a broader juridification of social life [34].

Consumerism in this specific context, i.e., health system and care, signifies reading and shaping the relationship between a consumer of service, in this case, the medical treatment and health care, or a product, medical devices or pharmaceuticals, and the provider of that service or product. Both health care products and services are commodities [35].

A proof of such consumerism approach is the right to freedom to move, recognised for patients, with the purpose of enjoying health services. For example, Article 56 TFUE has been used to establish a consumer-based right for an individual to travel to another Member State to receive services. The quintessential element is the remuneration for health care services. In the first cases that arose, such remuneration should be private only to the extent that the application of freedom to provide services. By contrast, in more recent cases it has been clarified the importance of the remuneration of the treatment has been clarified, and it is not relevant how the health system is organised. For example, in the pharmaceutical sector, the Court of Justice adopts a reasoning test on the notion of consumer-based market in pharmaceuticals, and the most important example is Duphar. It was held that the regulation

of medicinal preparations is subject to the rule of the free movement of goods due to the special nature of trade in pharmaceuticals. Therefore, Member States must be permitted to regulate the consumption of pharmaceuticals under national health system arrangements. The final purpose is ensuring the financial sustainability of health systems [36-38].

A different perspective arose from Kholl and Decker cases: these deal with the condition of authorisation of the Coordination Regulation. The question was whether the disputed national rules were consistent with the Treaty provisions on freedom to provide services or goods. The Court stated that the health care sector is subject to the provisions on freedom to provide services or goods; thus, it is considered an economic good. The conclusion was that rules under scrutiny do not deprive persons of the possibility of approaching a provider of services established in another Member State, since the costs incurred in that State are not reimbursed. Further, an ancient case – R. v Royal Pharmaceutical Society of Great Britain – demonstrates that if a national regulation is part of national health systems, member states possess a broader discretion to protect health in their territory [39-41].

This consumeristic approach to the healthcare system has been tempered, only apparently, by Directive 2011/24/EU about patients' rights in cross-border healthcare systems. This Directive responds to the uncertainty engendered by decisions of the Court of Justice relating to the right to receive cross-border healthcare services, under EU law on free movement of services. Directive 2011/24/EU prescribes that Directive 2006/123/EC does not apply to 'healthcare services, whether or not they are provided via healthcare facilities, and regardless of how they are organised and financed at the national level or whether they are public or private'. By contrast, the most recent case alludes to the protection of consumers from products harmful to health and shows increased respect for collective national public health principles, to reduce costs for health systems and suffering patients resulting from alcohol abuse [42-45].

It is worth emphasising that free movement of pharmaceutical goods is restricted because of consumer protection considerations. The 'patient-consumer' protection is co-ordinated at the EU level through four different categories of measures: manufacturing authorisation delivered by the authorities of one of the member States; a system of pharmacovigilance; labelling and packaging and advertisement; product liability governed by a no-fault compensation basis. All of these pieces of regulation are science-based or, better, grounded on 'a public policy mechanism for allocating power between experts and the lay public, among competing interest groups and between citizens and the state and for reducing or resolving conflict between interest groups with different views and preferences. The dark side alludes to the suppression of political debate. Thus, 'the EU regulation of pharmaceuticals may be said to be detrimental to the interests of patients (consumers) and providers of health care within the Member States' [46-50].

Despite the increasing consumerism approach to the health care sector, both positive and negative implications are presented. The synopsis is that consumerism in the health care sector, on one side, promotes autonomy and freedom of personal choices. These benefits, on the other hand, are limited only to certain patients, who can exercise autonomy and, consequently, choices [51].

Healthcare as a Fundamental Right in the European Union System

While the European Union's approach is driven by market and economic considerations, healthcare and the right to health are read as a fundamental right. According to Article 168 TFEU: '[a] high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities. Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission, and their prevention, as well as health information and education, and monitoring, early warning of, and combating serious cross-border threats to health. The Union shall complement the Member States' action in reducing drug-related health damage, including information and prevention.

Therefore, a high level of medical treatment should be assured, throughout the EU, evidently irrespective

of the nature – either public, or private – of the provider of the medical treatment. Moreover, healthcare is a special sector of the market, as it includes services of general interest and is financed largely from public funds. Whilst it is true, the health services market is affected by mechanisms based on which its operation is becoming closer to those governing any other economic (commercial) activity. In other words, medical service providers, like providers operating in other market sectors, strive to pursue their interests, compete on price and quality of their services and products.

Consequently, the problem is how to ensure protection of recipients of these services: it is uncontroversial that the patient should be subject to protection no less than that covering consumers of other goods and services. The main reason is that the healthcare sector deals with personal interests and rights of individuals, i.e., human life and health. Furthermore, running a business in such a specific industry requires meeting many conditions for medical treatments, including high professional qualifications, and therefore, entities providing such services should be required to maintain diligence and professionalism. These considerations, coupled with the very diverse nature of these services, the entities providing them, and the rules of financing, do not allow to come to a clear interpretation of this market [52].

From a historical perspective, in 2011, the paradigm shifted from patient to consumer when it was advanced the proposal to relax the rules of the Advertising Directive. The latter banned the advertisement of prescription medicine to patients to ensure the availability of and more accurate patient-oriented information. This theme is traditionally known as direct-to-consumer communication of prescription medicine (DTCC). The initial aim of the EU Commission was to enable patients and consumers to obtain information directly from industry about their condition and available treatment. The result was, and still is, that European patients are now able to access information about their diseases as well as medical treatment on the internet, through websites provided mostly by American companies. Despite this, the main goal of the Directive was to protect consumers against unfair contractual terms used by sellers and suppliers. The Directive also applies to trade, enterprises, and professions of a public nature; healthcare contracts are not excluded from the scope of this Directive. Thus, regardless of whether they are offered by entities from the private or public sectors, they are subject to the provisions of the directive [53-55].

Under Directive 2011/83/EU status of the patient is approached via different routes, simply because this Directive does not apply to the healthcare sector. More precisely, Article 3(1) stipulates that this Directive applies to any contract concluded between a trader and consumer where the consumer plays or undertakes to pay a price, including contracts for the supply of water, gas, electricity, or district heating, including by public suppliers, in so far as those goods are supplied under a contract. However, Article 3(3)(b) excludes its application to healthcare contracts as defined in Article 3(a) of Directive 2011/24/EU, whether they are offered through healthcare facilities.

Article 3(a) encompasses the definition of healthcare: 'health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices'. Health professional is defined in that Directive as a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in point (a) of Article 3(1) of Directive 2005/36/EC, or a person considered to be a health professional according to the legislation of the Member State of treatment". Article 3 (h) clarifies that patient means "any natural person who seeks to receive or receives healthcare in a Member State'.

Contracts excluded from Directive 2011/83/EU are, therefore, all those paid contracts relating to healthcare services provided by health professionals to patients for the purpose of assessing, maintaining, or improving their health state, including the prescription, dispensation, and provision of medicinal products and medical devices [56].

The legal framework is corroborated by Directive 2011/24/EU of the European Parliament and of the

Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (Directive), known as the Patient's Rights Directive (the PRD). The focus is on the rights of patients seeking cross-border healthcare, recollecting the different European case laws existing in this matter [57-58].

Ultimately, in the EU regulation, a subtle contradiction seems to exist; hence, on one side, the underlying political goal of the EU regulator is to promote a consumer approach to patients. On the other side, patients are not included in the Directive on consumers' rights. Additionally, the harmonisation of health policy achieves the aim of creating a European internal market. To elucidate, the European Union exercises its own power in this field via the adoption of binding laws that have the effect of improving health, so long as those measures are suitable for removing obstacles to trade or preventing distortion of competition [59]. These stances are reinforced by a further consideration: the PRD tries to strike a balance between the free movement of patients and the rights of Member States to protect the financial stability of their social security systems. Furthermore, the right to information of patients represents one main pillars, because patient choice is read as one of the core foundations of such Directive. To better explain, the patient choice becomes a positive development in specific circumstances in which patients want to make a decision based on their ethical convictions. Thus, the patient/consumer dichotomy seems to be omnipresent in the European Union law [60].

Moreover, recognising healthcare as a fundamental right signifies, de facto, promoting tourism in healthcare services. Consequently, the result is a consumerist approach to healthcare services rather than an approach that focuses on patient needs. An example of this is health services under different regulations among member states due to ethical and moral factors. In the reproductive sector, health tourism appears clear because on human reproduction matters, there are three alternative positions adopted by Member States: favour the choice of individuals; ensure protection of the children to be born, or protect the health of individuals concerned. For example, in SPUC v Grogan, the Court established that a medical procedure – abortion in the specific case – had the status of a service within the meaning of the EC treaty when performed legally in the member state in question [61].

Always in healthcare protection at the EU level, a further relevant legal provision is Article 114 TFUE, which provides for the general basis of the internal market. More in depth, paragraph 3 ensures the harmonisation measures to guarantee a higher level of protection of human health. More appropriately, Article 114 TFUE constitutes a fundamental legal basis for several EU interventions in the field of health, from the cross-border health directive to tobacco regulation. As regards the latter, Directive 2014/40/EU – together with Article 114 TFUE – is aimed at granting a higher level of human health protection through the prohibition of the placement of tobacco products on the market with a characteristic flavour. According to the same line of reasoning, as regards electronic smoke, the Court of Justice of the European Union stated that the aim of the EU Regulation is not to obtain a higher level of human health protection as a general objective, but, more appropriately, it constitutes an obligation [62].

To value appropriately the right to health in the European Union, it is quintessential to read Article 114 TFUE together with Article 168, paragraph 2, TFUE. From this legal framework appears an increasing attention to public health in the European Union appears, including the rights to health protection and healthcare services. This means, among others, improving the quality of the working environment, enhancing consumer protection, and protecting the environment [63-64].

To sum up the described legal scenario, Article 114 TFUE empowers the EU to adopt measures to ensure the functioning of the internal market. Thus, regulating health care, despite its increasing value as a fundamental right, means, de facto, regulating the internal market in specific areas, i.e., pharmaceuticals, medical devices, consumer product safety, tobacco, and food regulation.

Finally, the conclusion seems to be the following: while the EU's purpose is to shape the right to health as a fundamental right, the regulation promotes a consumerist approach in the health care sector. For example, one of the goals of the PLD is, among others, ensuring 'that consumers' health and property are afforded a high level of protection'. In addition, the

regulatory methodology adopted by the EU legislator in the field of medical devices is aimed at removing technical barriers to trade in Europe. This conclusion is corroborated by the underlying rationale of MDR: creating a new certification with requirements (such as an obligation for the manufacturer of a new role) and stricter measures about post-market surveillance and vigilance. A medical device may be defined as a market-funded, primarily, by investment in such sector, pursuing the objective to provide patient with sufficient autonomy in managing their own health [65-67].

From the Healthcare Market to the Cryonics Market

One of the most significant changes occurring in developed countries is a shift of medical care from curative to preventive services. The attention is focused on the control of illness prevention: when such activity, prevention, is emphasised, the client must be persuaded that he has a need for medical services such as a periodic check-up. Thus, there are some elements typical of a 'buyer's market' which are the expression of a tendency to customise the patient, who becomes a client, essentially. Where a patient becomes a client, he/she may be treated as an object: because of this, there is also a sea-change in the relationship with health staff. The primary consequence of this new healthcare relationship pertains to the medical information that is converted into medical orders. Hence, if a patient requests more information, doctors are often reluctant to provide it [68-69].

Nevertheless, the health care world, from an economic perspective, is a monopolistic market where there is a 'monopolistic competition'. The justification is the pervasive effect of illness on patients [70]. The latter, in their weakness, in their vulnerability, in their fear, patients crave the solace of doctors, confide themselves to doctors, and trust doctors. Patients want a therapeutic relationship with their doctors, a relationship that produces and prospers on reliance, attachment, and confidence [71].

This generates a system called 'inherently monopolistic' in which '[t]he doctor dictates what brand [of drugs] the patient is to buy . . . [and] orders the amount of drugs and prescribes the quantity to be consumed. In other words, the patient is a captive consumer. There is no other profession or business where a member thereof can dictate to a consumer what brand he must buy, what amount he must buy, and how fast he must consume it, and how much he must pay, with the further condition to the consumer that any failure to fully comply must be at the risk of his own health. The patient then becomes a totally captive consumer, and the doctor has a monopoly. This monopoly is also boosted by the general lack of awareness that often affects all contractual and economic transactions [72-74].

Within cryonics, the market shall be defined as monopolistic because the organisations are limited in number, and the health treatment that they offer is not offered by the public national service. Consequently, not only must a potential cryo-patient allocate a significant amount of money to be cryopreserved, but also this treatment is not chosen by large numbers of people [75].

The different cryo-companies operating in this niche market use different terminology to refer to their human members who sign this contract. For example, Alcor Life Extension Foundation speaks about "Member"; by contrast, Cryonics Institute and Oregon use the term "patient". The relationship between an organisation and the future cryo-patient has its roots in an agreement signed between these two parties. Although this terminology is not encapsulated in official documentation yet, it is possible to infer that the first party can be defined cryo-patient, whereas the second one is a cryo-service provider. Currently, it is possible to analyse only the American version of this agreement, since the Kriorus agreement is available exclusively in the Russian language. The only agreement in English is the one encompassed by the framework provided by Alcor Life Extension Foundation. This contract is named by Alcor as a Cryopreservation Membership Agreement; it consists of three sections: the funding, Alcor's obligations, and the member's obligations [76-77].

The first section alludes to funding itself, the required fees, and the payment terms. It states that there are at least two categories of funds: Cryopreservation Funding Minimum (CFM) and Comprehensive Member Standby (CMS). The CFM encompasses two types of cryopreservation funding, more specifically, Regular Cryopreservation Funding and Lifetime Cryopreservation Membership Funding. Having said that, it is also important to highlight that Alcor reserves its

right, at its sole discretion, to change the amount of the required Cryopreservation Funding Minimum, to meet any increased costs or to cope with other needs, such as, but not limited to, an increased inflation rate [78].

This agreement model is like the other used by Cryonics Institute and Oregon Cryonics, two other cry-organisations. The main idea is that the cryonics organisations have the obligation to preserve human remains using their best judgment, or their good faith, or a discretionary approach to the matter. Furthermore, these organisations are not responsible for any problems relating to the patient's cryopreservation or to any federal, state, or local status, or, moreover, for any regulation, ordinances, or governmental or judicial directives. Furthermore, the only parameters are the good faith and the best judgment of the organisations [79-81].

The cryopreservation agreement involves the notion of anatomical donation of human remains, also referred to as "last will for human remains". In the Oregon Cryonics' document, it is defined as a "gift" for both research and educational purposes. From this specific "gift," some direct consequences arise. In the first place, the patient will not receive monetary compensation or valuable consideration for it. Secondly, the individual authorises testing, accessing, and reporting on his human remains. Ultimately, this agreement – although this is not totally clear - covers only education and research purposes, rather than the cryo-patient's resuscitation or revival.

Conclusions

The research question of this work is how we can define the patient under nitrogen: cryo-patient or cryo-client, so cryo-consumer. The patient, whom we define as a cryo-patient, may choose between whole-body preservation and the preservation of the head only (neuro-preservation). The last one seems to be an option for those who believe that the identity of a person is the brain, and they hope that in the future the living being may rely on a 'human' head, albeit in an artificial body. The question – once again – is to ascertain what the real legal status of this individual is in this phase, i.e., before signing the cryoconservation agreement and during his time under liquid nitrogen [82].

Potentially, within a cryonics agreement, it would be possible to distinguish between cryo-client and cryo-patient. The first one is the counterparty to the cryonics provider when the agreement is signed. The second one, the cryo-patient, may be the individual under liquid nitrogen, i.e., the frozen individual. According to this categorisation, the cryo-client may have the features of a consumer; thus, the consumer protection regulations should be applied. By contrast, the cryo-patient may be categorised as purely a patient, rather than a consumer.

The just highlighted difference is totally aligned with the linguistic meaning of patient and consumer. From an etymological perspective, the word patient comes from pati or pătĕre, a Latin verb, whose meaning is "suffer" or "to suffer". Consequently, a patient, also from a literal view, is an individual who is experiencing suffering. By contrast, 'consumer', also from Latin, means to use and was adopted to stress a more active role by the individual in his/her interaction with the physician. It is this last element that distinguishes the two figures: the patient figure, indeed, is painted by an aura of passivity. To further elaborate, a patient is in a position in which he/she has only a spectator's role, because the main actor is either their illness or the physician [83].

If this line of reasoning were applied to the cryonics market, it would become obvious that the human who signs a cryonic contract is not a patient, but rather a consumer: he would be able to choose the best companies that offer this treatment. Additionally, he/she would also be able to negotiate the whole service, to choose the procedure and, if required, to buy the package for the whole family, including animals (such as cats, dogs, rabbits, and so on). What is highlighted above shows that cryonics, from this perspective, is not a medical treatment but, more precisely, a commodity, a wellness treatment to fight death. Moreover, underlying cryonics, there is a self, individual, and singular view of life; thus, the concept at stake needs to be encompassed within the main area of human enhancement. In its turn, the latter encapsulate "biomedical interventions that are used to improve human form or functioning beyond what is necessary to restore or sustain health"[84-85].

Arranging for a cryopreservation service requires a complex contractual negotiation with the consumer.

Such contractual activity is aimed at confirming the consent, agreement of the services provided and their scope, the role of a potential surrogate while the consumer is in suspended animation, and the circumstances under which the consumer will be resuscitated. Moreover, services may cover, also, the intervention of third parties, such as an attorney whose role will be supporting and assisting the consumer, i.e., the counterparty of the cryo-organisation, to deal with their assets and other legal considerations, as well as family members or friends who may be implicated during the suspended animation or post-cryopreservation period [86-87].

The synopsis is that cryonics agreement emphasises the difference between consumer and patient in the contemporary health care system, even more affected by IT and scientific development. Paradoxically, the European Union approach seems to appreciate a consumerist approach also to the health care sector. Whereas the cryonics market requires distinguishing between consumer and patient, the demarcation line is the beginning of the conservation under nitrogen. Therefore, when an individual is approaching a cryonics, organisation intending to sign an agreement, he/she is a consumer; by contrast, when the treatment commences, he/she becomes a patient.

To elucidate, cryonics suggests bifurcating the legal identity of an individual: the latter, in signing the contract of cryonics, is a consumer, engaged in a speculative biomedical service. By contrast, the same individual, as a cryopreserved body or head, should be better understood as a patient. Such a distinction is quintessential since the contractual party is the counterparty, indeed, of the cryonics organisation. On the opposite side, the cryonics organisation has custodial care of the cryopreserved body. Thus, a cryo-consumer/cry-client is a person who has opted for cryopreservation as a service; a cryo-patient is who is under liquid nitrogen [88].

Consequently, in the cryonics market, the distinction between cryo-consumer and cryo-patient mirrors how the technological development in the healthcare sector requires to shift in the paradigm from patient to consumer. In cryonics, this distinction is helpful to clarify the exact role played by the individual, distinguishing the contractual phase from the execution of the contract.

This conclusion appears to be coherent also with recent developments in EU law, including the New Product Liability Directive, which reinforces the notion that users of medical products are to be treated as consumers entitled to enhanced protection. This stems from their inherent vulnerability and the asymmetry of information and power in biomedical transactions. This paradigm should be applied to cryonics, too. Hence, cryonics, as a speculative and largely unregulated practice, falls within this model: the individual who contracts for cryopreservation engages with a service that mimics medical intervention and invokes future therapeutic potential. Further, they may be legally framed as a consumer under evolving product liability frameworks, even if the 'product' in question is a preservation protocol rather than a conventional device or drug. There are two main justifications. The first one is that both medical law and consumer protection frameworks recognise, increasingly, individuals using biomedical products and services as consumers, due to their inherent vulnerability. The second one deals with the New Product Liability Directive, which extends enhanced safeguards to those engaging with medical technologies [89].

To sum up everything, in the cryonics market, the cryo-consumer is the individual who enters into a speculative biomedical agreement, whereas the cryopreserved individual remains symbolically framed as a patient, despite lacking legal personhood.

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ary principle in the second sentence of Article 35 of the Charter, Article 9 TFEU and Articles 114(3) TFEU and 168(1) TFEU which require it to ensure a high level of protection of human health in the definition and implementation of all Union policies and activities'. CJEU Case C-477/14 Pillbox 38 (UK) Ltd v The Secretary of State for Health ECLI:EU:C: 2016:324 para 116.

65. Article 168 TFUE, in essence, requires to guarantee, at least, six main factors in public health, such as: 1) definition and implementation of all policies and activities of the EU with a view to improving public health, preventing human diseases and ailments, and removing sources of danger to physical and mental health – including combating pandemics by promoting research into their causes, for example; 2) to reduce the harmful effects of drug abuse on health, including information and prevention; 3) to improve cooperation between Member States in the field of health as well as supporting their actions by encouraging cooperation between them to increase the complementarity of their healthcare services in border regions; 4) to develop cooperation among countries and international organisations competent in the field of public health; 5) to promote the described objectives by adopting not only measures that set high standards of quality and safety for organs and substances of human origin, blood and blood derivatives, including the veterinary and phytosanitary fields; 6) to incentive measures designed to protect and improve human health; measures concerning monitoring, early warning of, and combating serious cross-border threats to health; and measures that are directly intended to protect public health in relation to tobacco and alcohol abuse; 7) to adopt recommendations for the attainment of the objectives set out in Article 168 TFEU.
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76. 'Unlike a person shopping for a car, a suit, or a haircut, does not know what it is they [sic] need, what it should be paid for, how much good the treatment really did. Instead of a clear specification of what is to be expected from both parties, the doctor is to do what is right and to bill fairly for the necessary care. Thomas E. Getzen, Health Economics and Financing (Wiley 1997) 114.
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