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Multidisciplinary Issues on Scientific Research and Medical Treatment on Infants in Comparative Law

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MULTIDISCIPLINARY ISSUES ON SCIENTIFIC RESEARCH AND MEDICAL TREATMENT ON INFANTS IN COMPARATIVE LAW

Elena FALLETTI[1]

Résumé

L'article examine les solutions adoptées par le droit italien et anglais, à certaines questions inhérentes à la recherche scientifique pédiatrique qui ont suscité un vif débat tant sur le plan médical que sur le plan éthique et juridique. Les essais cliniques sont calqués sur des patients adultes, dont les paramètres corporels et métaboliques sont très différents de ceux des enfants. Par conséquent, des doutes éthico-juridiques se posent quant à la mise en balance des droits opposés de l'enfant : est-il légitime de tout tenter pour la survie d'un enfant ? Même si cela signifie que l'enfant devient un « animal de laboratoire » pour la recherche ? Sinon, le destin est la mort. Dans cette situation, comment est-il possible d'identifier "l'intérêt supérieur" de l'enfant ?

Mot clés : *recherche scientifique pédiatrique — consentement médical — l'intérêt supérieur" de l'enfant — soins de soutien aux fonctions vitales.*

Abstract

This article investigates some questions inherent to scientific paediatric research that have given rise to an international medical and ethical-juridical debate, particularly in the British and Italian legal systems. Clinical trials are modelled on adult patients, who have very different body and metabolic parameters from those of children. Therefore, ethical-juridical doubts arise regarding the balancing of opposing rights of the child: is it legitimate to try everything possible for a child's survival? Even if this means the child becomes a

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guinea pig in research? Otherwise, the fate is death. In this situation, how is it possible to identify the child's "best interest"?

Keywords*: paediatric research — informed medical consent — best interest of the child — life support.*

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Introduction

The aim of this paper concerns the moral doubt about whether infant patients suffering rare diseases should be subjected to scientific research and clinical trials in the absence of tested scientific protocols. The primary purpose of scientific clinical trials is knowledge enhancement, aimed at trying new therapeutic possibilities, and improving patients' health conditions at the same time.[2] In this regard, the question should be: does this aspect of scientific research take on a different value if it refers to children? Generally speaking, clinical trials in scientific research consist in clinical activity aimed at scientific progress. They concern innovative medical-surgical procedures, both diagnostic and therapeutic, which have not yet been shared as proper protocols used by the scientific community.

Today there is a kind of diffidence towards clinical trials involving infants, due to a risk perceived as unacceptable opposed to the certainty that scientific achievements now available are the best ever and definitive ones. Scientific experimentation in research for drugs targeting infants is low[3], especially newborns[4], since people are no longer familiar with uncertainties due to

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[2] Marshall, Patricia. 2006. Informed Consent in International Health Research*, J Empir Res Hum Res Ethics (1):25-42.*

[3] Park, Jay JH, Grais, Rebecca, Taljaard, Monica, Nakimuli-Mpungu, Etheldreda, Jehan, Fyezah, Nachega, Jean B, Ford, Nathan, Xavier, Denis, Kengne, Andre P, Ashorn, Per, Socias, Bhutta, Zulfiqar A, and Mills, Edward J. 2021. Urgently seeking efficiency and sustainability of clinical trials in global health, *The Lancet Global Health*, 9 (5):e681-e690; England, Amanda, Wade, Kelly, Smith, Brian, Berezny, Katherine, and Laughon, Matthew. 2016. Optimizing operational efficiencies in early phase trials: The Pediatric Trials Network experience, *Contemporary Clinical Trials*,47:376-382.

[4] Neonates, infants up to 28 days of age, are an understudied population. "*Nearly 40% of the drugs involving neonates pursuant to paediatric legislation between 1997 and 2010 were deemed safe and effective in neonates. (...) Normally neonates are enrolled in pharmacokinetics, pharmacodynamics, safety, and dose-finding studies; once an appropriate dose is established, safety and efficacy studies may be done. The sample size for most neonatal studies in very small due to the limitations inherent to these trials, including low study consent rates for parents of vulnerable infants, limited blood volume available to conduct pharmacokinetic studies, (…), lack of availability of sensitive drug concentration assays from very-small-volume specimen (e.g. dried blood spots), and lack of robust clinical end points*" (Laughon, Matthew M, Avant, Debbie, Tripathi, Nidhi, Hornik, Christoph P, Cohen-Wolkowiez, Michael, Clark, Reese H, Smith, Brian, and Rodriguez, William. 2014. Drug labeling and exposure in neonates. *JAMA Pediatr.* 168(2):130-136; Laughon, Matthew M, Benjamin, Daniel K Jr, Capparelli, Edmund V, Kearns, Gregory L, Berezny, Katherine, Paul, Ian M, Wade, Kelly, Barrett, Jeff, Smith,

sudden illness or death: they think it might happen to someone else, or at least there is a (scientific or medical) remedy available that is safe and reliable. Indeed, the difference between the past and the present lies in the involvement of infant patients in experimental procedures, which was much more common in the past[5], and much more difficult today. Nowadays, there would seem to be a contradiction: on the one hand, there is a very high level of attention to the protection of infants, apparently for their benefit, but on the other hand, when dealing with their wellbeing, parents or caregivers get scared, even if it is in children's interest. If science had not advanced, the infant mortality rate would be very high again. Now bioethics calls for the protection of children, treating them in the same way as mentally ill persons, who are not capable of self-determination, and are among the categories most at risk of abuse by doctors.

The main legal issue in this area is the expression of medical informed consent by the representative of the infant patients, since medical consent regards the intrusion in the child's personal sphere, both in the physical and the psychological sense. The paediatric clinical trial is a specific scientific research area, as infant patients subjected to this procedure do not have capacity to express their informed consent autonomously, due to their young age. This is an essential point: can medical informed consent ethically and legally be expressed in paediatric scientific research and clinical trials?[6]

The risk of decisions influenced by medical paternalism is more present in situations involving children, since the doctor-adult patient relationship sees

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Phillip Brian, and Cohen-Wolkowiez, Michael. 2011. Innovative clinical trial design for pediatric therapeutics, Expert Rev Clin Pharmacol.4(5):643–652; Ward, Robert M and Sherwin, Catherine M T. 2015. Ethics of Drug Studies in the Newborn, *Pediatric Drugs,* , (17):37-42.

[5] Barnes, Diana. 2012. The Public Life of a Woman of Wit and Quality: Lady Mary Wortley Montagu and the Vogue for Smallpox Inoculation, *Feminist Studies,* 38, (2) 330–362; Huerkamp, Claudia. 1985. The History of Smallpox Vaccination in Germany: A First Step in the Medicalization of the General Public. *Journal of Contemporary History,*20(4):617-635; Juskewitch, Justin E., Tapia, Carmen J, and Windebank, Anthony J. 2010. Lessons from the Salk Polio Vaccine: Methods for and Risks of Rapid Translation, *Clinical and Translational Science*, 3, (4):182-185.

[6] Kodish, Eric. 2003. Informed Consent for Pediatric Research is it Really Possible? *Journal of Pediatrics* 142(2): 89-90; Bester, Johan and Kodish, Eric. 2017. Children Are Not the Property of Their Parents: The Need for a Clear Statement of Ethical Obligations and Boundaries. *The American Journal of Bioethics* (11): 17-19.

an exchange of information based on trust, rather than a power relationship, typical of paternalism.[7]

In the most controversial cases, medical trials on very rare diseases represent the last available hope for parents: they are facing the certain death of their child. Therefore, an irrational balancing act often occurs: on the one hand the risk of the child becoming a guinea pig, on the other hand, the certainty of the child's death occurring within a short time.

Scientific paediatric research ethics requires that the best interest of the child[8] takes precedence over the concept of autonomy,[9] since, on the one hand, infant children cannot express valid consent, and on the other hand, parents and researchers play a different role in paediatric ethics compared to the ethics of consent expressed by adults[10]. Here, the question of "*who decides*", so relevant in the ethics of adults, is less evident regarding minors, where the focus is on "*which decision*" is best for the child.[11]

Many children cannot participate in the discussion about their involvement in the research. Indeed, even those who are able to participate in this decision are not able to fully understand the risks and benefits. So, all the people involved (parents, doctors and scientists) have a duty to protect child patients from the dangers of an experimental medical treatment, but at the same time they also have the hope of advancing science and the discovery of a new therapy for the childhood disease. This point represents a tension between two inevitably conflicting purposes: protection and progress.[12]

This topic represents a relevant ethical issue, which must be taken into account, namely the low number of drugs for infants; since the younger the

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[7] Kodish, Eric cit.

[8] Lamarque, Elisabetta. 2016. *Prima i bambini. Il principio dei best interests of the child nella prospettiva costituzionale*, 1st edition, 21 ss. Milan: Franco Angeli.

[9] Kodish, Eric, cit.

[10] Varadan, Sheila. 2020. Article 5: The Role of Parents in the Proxy Informed Consent Process in Medical Research involving Children, *The International Journal of Children's Rights* 28(3): 521-546.

[11] Bester, Johan and Kodish, Eric, cit. 18.

[12] Laventhal, Naomi, Tarini, Beth, Lantos, John. 2012. Ethical Issues in Neonatal and Pediatric Clinical Trials, *Pediatrics Clinics*, (59):1205-1220.

children are, the less willing parents are to submit their children to clinical trials, consequently the number of appropriate drugs available for them will be lower.[13] This means that drugs for adults may be prescribed to infants, even if this could represent a serious risk for the youngest patients' health.[14] At this point, it would be necessary to distinguish off-label[15] drugs from off knowledge,[16] ones, whose effects are completely unknown. In this matter, physicians would be required to discuss therapeutic decisions thoroughly with the parents of infant patients,[17] but comparative case law experience illustrates that controversial situations could emerge precisely between these two important opposing parties at the scene of therapeutic choices: the infants' parents and physicians.

The aim of this article is to compare the English and Italian legal landscapes on scientific research on very young infants, since these cases presents legal claims regarding the survival of the children involved.

This article begins exploring the relationship between medical informed consent and possible conflict of interests among parties: scientific and medical staff with parents and public authorities representing the involved infants. Then, it focuses on the international and national regulations and, especially on EU Regulations, English Common Law, and Italian law. Furthermore, the paper analyses the European Court of Human Right's case law about informed consent on scientific research. Finally, it points out cases in both English and Italian case law about infants involved in legal claims regarding

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[13] Yackey, Katelyn, and Stanley, Rachel. 2019. Off-Label Prescribing in Children Remains High: A Call for Prioritized Research. *Pediatrics.* 144(4):e20191571

[14] Fernandez, Eva, Perez, Raul, Hernandez, Alfredo, Tejada, Pilar, Arteta, Marta, and Ramos, Jose T. 2011. Factors and Mechanisms for Pharmacokinetic Differences between Pediatric Population and Adults, *Pharmaceutics* 3, (1);53-72.

[15] "Off-label" means that the dose, the population treated, the duration of treatment, or the efficacy has not been established"(England, Amanda, Wade, Kelly, Smith, Phillip Brian, Berezny, Katherine, and Laughon, Matthew, 2016. Optimizing operational efficiencies in early phase trials: The Pediatric Trials Network experience, *Contemporary Clinical Trials,* (47):376-382).

[16] Ward, Robert M and Sherwin, Catherine M T, cit.

[17] Ward, Robert M and Sherwin, Catherine M T, cit.

the suspension of their life support, or submitted to palliative care, instead of being involved in scientific trials.

1. ETHICS, MEDICAL INFORMED CONSENT AND CONFLICT OF INTERESTS IN PAEDIATRIC CLINICAL TRIALS

Historically offspring were long considered "property" of their parents, who could dispose of them as if they were "assets" (chattel) belonging to them.[18] However, nowadays both ethics and legal rules discipline the expression of medical consent by parents as legal representatives of the infant children. This is conceptually different from the manifestation of informed consent. Indeed, in the field of paediatric clinical trials, parents act as representatives but they could have a conflicting interest with that of their children, who are the represented persons.

The American debate on clinical trials ethics strongly influenced scientific and medical practice in the Western Legal Tradition. One of the first and most relevant cases about ethics in clinical trial issues was the so-called Tuskegee Syphilis Study,[19] especially after the publication of the "Belmont Report" in 1979, that revealed it to the public opinion. After that, in the paediatric field, it is worth recalling the trial carried out at Willowbrook State School in Staten Island in 1967, where, without informing the parents, children with mental disabilities were inoculated with hepatitis in order to study its course.[20] The Willowbrook State School case opened up an important debate about the

[18] Bester, Johan and Kodish, Eric. 17.

[19] It lasted from 1932 to 1972 and concerned the observation of the course of syphilis in black patients, who were never given the treatment, discovered in the meantime, until their death (JonesHoward. 1993. *Bad Blood: The Tuskegee Syphilis Experiment,* 2nd edition, 5 ss.New York; The Free Press; Corbie-Smith, Giselle Thomas, Stephan B., and St. George, Diane Marie M. 2002. Distrust, race, and research, *Archives of Internal Medicine*, 2458-2463.

[20] Laventhal, Naomi, Tarini, Beth, and Lantos John, Ethical Issues in Neonatal and Pediatric Clinical Trials, Pediatrics Clinics, 2012, 59, 1205-1220.

manifestation of informed consent and the possibility of infants undergoing clinical trials.

This discussion has grown both in the United States and in Europe, producing debate on important ethical principles such as respect for persons,[21] including infants. On this point, it should be noted that infants are characterized by a different physiology from adults. Trials involving them and, above all, the follow-up of innovative treatments require a longer time to verify the consequences and side effects of experimental treatments administered.[22] This aspect is relevant because it concerns the relationship between the level of risk in trials and the vagueness of the risk itself, since it cannot always be fully known.[23] In this aspect it is part of the principle of justice, which in clinical trials indicates that the risks and benefits of research must be distributed fairly and not disproportionately among the groups of participants.[24]

This is a significant problem given the difficulty in obtaining parental consent for recruitment into paediatric clinical trials. For example, in an innovative treatment, as in the Gard case discussed below, the relationship between the parents of the infant patient and the medical staff conducting the research is essential. If there is a disagreement between clinicians, this must be resolved; if it disrupts the conduct of the trial, it must be stopped.[25] This is because "*research must be done in authentic pursuit of answers to valid clinical questions, and patients should not be subjected to research risks in the absence of genuine belief that the answer to the research question is unknown"*.[26]

What are the possible conflicting interests in these cases? First of all, there is a conflict between the best interest of the child and that of the parents, especially as regards the emotional aspects. Conflicts of interest of an economic nature could also arise (such as for example in relation to fundraising among

[21] Ward, Robert M, and Sherwin, Catherine M T, cit.
[22] Ward, Robert M, and Sherwin, Catherine M T, cit.
[23] Laventhal, Naomi, Tarini, Beth, and Lantos, John, cit.
[24] Ward, Robert M, and Sherwin, Catherine M T, cit.
[25] Laventhal, Naomi, Tarini, Beth, and Lantos, John, cit.
[26] Laventhal, Naomi, Tarini, Beth,and Lantos, John, cit.

the public, which could easily be organized through social networks) or of a moral nature (the emotional condition and distress with respect to the situation of the loved one) at the implementation of the interruption of medical treatment, as in the withdrawal of life support,[27] or of a possible scientific clinical trial.

Detecting the potential conflict of interest of the child's prospective representative would be necessary, since divergent interests in both parties might emerge, as the coincidence between the representative's initiative and the interest of the represented person is not sufficient for excluding conflicts of interest. Generally speaking, the infant's parents have at the same time the responsibility, the right, and the duty to take decisions concerning him/her. So, a further question occurs: whether they are able to make the most appropriate decision for their young child on health issues. On the other hand, there is a public duty of society, understood as a community, to protect children from decisions of their parents that may be dangerous or inappropriate.[28] In the case where the representative has an interest in competition (even if not conflicting) with the represented person, the rules on representation must be applied.

2. SUPRANATIONAL REGULATIONS ON SCIENTIFIC RESEARCH AND MEDICAL CONSENT

A clinical trial aims both to obtain the well-being and improvement of the patient's health conditions and to participate in a collective project that could contribute to the development of general knowledge. An implicit expectation hides itself behind these benefits related to "sacrifice" of the single patient for the benefit of the whole society. How does this approach stand towards a child?

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[27] Santosuosso, Amedeo, and Turri, Gian Cristoforo. 2006. La trincea dell'inammissibilità dopo tredici anni di stato vegetativo permanente di Eluana Englaro*, La nuova giurisprudenza civile commentata,* 5(1): 477-485.

[28] Kodish, Eric, cit.

Under a philosophical perspective, a clinical trial involving an infant "candidate/participant" affected by a rare disease deserves a restrictive and rigorous Kantian approach, according to which it is morally unacceptable to transform a human being, especially a child, into an instrument in order to help other members of society to improve their condition.[29] At the opposite, and more permissive approach, there is J.S. Mill's perspective, according to which the utilitarian aspect of clinical trials would justify the "sacrifice" of the child for the benefit of society.[30] However, this path appears in contradiction with J. S. Mill's well-known libertarian position according to which "*Over himself, over his own body and mind, the individual is sovereign*."[31]

A. The Oviedo Convention on the expression of medical consent in scientific research

The most important European regulation on scientific research and medical treatment is established by the Oviedo Convention on Biomedicine of 1997,[32] whose Chapter V is devoted to experimental treatments, subsequently completed by the Second Protocol approved in 2004. The aim of the Convention as defined in Article 1 is to *"protect the dignity and identity of all human beings and guarantee everyone respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine*".

According to Article No. 2 "*the interests and welfare of the human being shall prevail over the sole interest of society or science*". This principle is very general and aims at avoiding any kind of exploitation of the patient, especially in the interest of third parties such as family or physicians and scientists in managing the economic resources. It could be possible that decisions

[29] Kodish, Eric, cit.

[30] Kodish, Eric, cit.

[31] Mill John Stuart. 1859. On Liberty, London, John W. Parker and Son, West Strand.

[32] Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4.4.1997, entry into force 1.12.1999.

concerning end of life are involved, since in many situations refusing medical treatment could cause the death of the patient. In these cases, the protection of dignity imposes that the patient must be at the centre of the health provision and his or her wishes, when possible, must be taken into account. If the person's wishes cannot be determined, the pursuit of the best interest of the child patient "implies that the decision take account of his/her well-being and quality of life [...] which may take precedent over treatment which has become futile or disproportionate."[33] Indeed, Article 6.2 of the Oviedo Convention establishes that "*where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law*". In any case, the severely ill patient should not to be abandoned:[34] he or she must have access to the most appropriate care for the kind of condition, accessing pain treatment, necessary nursing care and palliative care.

According to the Explanatory Report of the Oviedo Convention, physicians are not always bound to respect the opinion of the incapable or incompetent person's legal representative, because they have to act following "the best interest of the person", even if this means acting in a different way,[35] through a court decision, for instance. Nevertheless, according to some scholars, a court decision does not seem to be the best solution for incompetent or incapable persons. Indeed, a doctor should know his or her patient and his or her personal and therapeutic experiences with all related clinical and psychological problems, so, he or she is in a better position to decide on the specific case than a third party, such as a judge, who is aware of only some elements of the specific case.[36] In this sense, some scholars have serious

[33] Relation to the Principles of the Convention on Human Rights and Biomedicine, Symposium on decision making process regarding medical treatment in end of life situations, 30 November – 1 December 2010, Palais de l'Europe, Strasbourg, France, https://rm.coe.int/end-of-life-compilation-e/1680998932 (last accessed on 7 December 2021).

[34] Council of Europe. 2014. Guide on the decision-making process regarding medical treatment in end-of-life situations, 16. Strasbourg.

[35] Pavone, Ilya Richard. 2009. La Convenzione Europea sulla Biomedicina, 1st edition, 141-15. Milan, Giuffré.

[36] Pavone, Ilya Richard, cit.

doubts about the opportunity of judicial intervention in such a sensitive area, highlighting the risk of legalization of medical decisions.[37]

However, on the one hand, there is the physician's ability or material capacity to treat, and, on the other hand, there is his or her power to treat. In the absence of the patient's consent, even if the physician actually possesses the professional competence to properly enforce the therapy, he or she does not have the full power to treat. These two operational levels should be separate. The first one is related to the technical and professional feasibility of providing care based on the best science and experience available; while the second one is related to the authority required in order to legitimize the application of the available medical treatment. Only the patient may attribute this authority to the doctor through his or her manifestation of informed consent, and this same authority ceases the moment in which the patient refuses or withdraws such consent.[38]

According to these rules, clinical trials should not be arbitrary, but protect the human being in his/her dignity, physical, and mental integrity.[39] Specifically, article 17 concerns the "*Protection of persons not able to consent to research*". The combined provisions of articles 5, 6, 15 and 16 prevent the research from being undertaken unless the expected results entail a real and direct benefit to the health of the person concerned, who could also be a person unable to express his or her consent. In any case the subject can always refuse or withdraw such consent.

This approach is applied both in the therapeutic scientific research carried out in the paediatric field and in adults with very serious mental deficiencies.[40] It should be noted that during the drafting of the Convention on Biomedicine the question was posed for the case of those individuals incapable

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[37] Gevers, Jan. 2004. The European Court of Human Rights and the Incompetent Patient. *Eur J Health Law* 11: (225-229).

[38] Comitato Nazionale per la Bioetica (Italian Bioethic National Committee). 2008. Rifiuto e rinuncia consapevole al trattamento sanitario nella relazione paziente-medico. 7. Rome: Presidenza del Consiglio dei Ministri, www.governo.it/bioetica (last accessed on 7 December 2021).

[39] Bompiani, Adriano. 2009, *Consiglio d'Europa, diritti umani e biomedicina.* 92. Roma: Studium.

[40] Bompiani, Adriano, cit.

towards whom the application of the research could not bring direct benefits.[41] Indeed, the second paragraph of article 17 exceptionally admits, and subject to the law, the feasibility of a research on incompetent person where results "*did not bring direct benefits to the health of the person concerned, but served to significantly improve the scientific knowledge that could have positive repercussions also for the same subject or for others belonging to the same nosographic category, provided that the research offered only minimal risk and annoyance to the person involved."*[42]

However, this approach could be unsuccessful with respect to the protection of the best interest of the child, in particular to the child's interest in not being exploited for scientific purposes or to improve knowledge. On this point, in order to protect human dignity, the Explanatory Report prescribes that the requirements to protect the dignity of people without capacity to give consent, *"namely only minimal risk and minimal burden for the individual concerned.*"[43] Indeed, the right to health, in the light of the best interest of the child, must consider children as holders of their own rights, since "*special emphasis has been placed on child-friendly health services, which regard children as rights holders, and position their rights, needs, voices and evolving capacities at the center of healthcare policies and practices.*"[44]

Regarding the expression of informed medical consent in the field of paediatric scientific research, there is a coherent approach in the relationship between supranational and national courts. In this sense, the European Court of Human Rights has stated that it is not its task to take the place of the competent national authorities to determine the level of risk acceptable to patients who intend to access compassionate care in the context of an

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[41] Bompiani, Adriano, cit.

[42] Bompiani, Adriano, cit.

[43] Council of Europe, European treaty series – no.164, E*xplanatory report to the convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: convention on human rights and biomedicine*, 1997, https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164?module=treaty-detail&treatynum=164 (last accessed on 7 December 2021).

[44] Liefaard, Ton, Hendricks, Aart, and Zlotnik, Daniella. 2017. *From Law to Practice: Towards a Roadmap to Strengthen Children's Rights in the Era of Biomedicine*, 1st edition, 19. Leiden, Universiteit Leiden.

experimental therapy.[45] On the other hand, the English judges underline that the point of view to be referred to is that of the child and that the protection of his/her well-being is the decision-making parameter.[46] This is a wide margin of appreciation recognized by the European Court of Human Rights,[47] provided that the measures adopted are proportionate, meticulous, decided after taking into consideration evidence produced by first-rate experts, with the possibility of carrying out the three levels of judgment through clear and reasoned reasoning.

B. European Union law

Under the EU law, an important legal text of reference is the Charter of Fundamental Rights of the European Union.[48] The starting point of the Charter is to consider the dignity of the person as an essential parameter of the person's legal protection. Dignity is an essential component of the human being; it identifies with the person and belongs to everyone without any distinction.[49] In this context dignity plays a leading role in the legal reasoning for the protection of health and childhood, in particular in scientific research.

In this regard, it is not *"possible to make human matter become an instrument from the point of view of human dignity since the human body represents its carrier."*[50] If on the one hand the introduction of the positive obligation to respect and protect human dignity is a specific duty for both the

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[45] ECtHR, 13 November 2012, Hristozov and others v. Bulgaria, ric. n. 47039/11 318/12; ECtHR, 28 May 2014, Durisotto v. Italy, ric. n. 62804/13.

[46] [2005] EWCA Civ 1181, (UK), Wyatt v. Portsmouth NHS Trust.

[47] ECtHR, Hristozov and others v. Bulgaria, cit.

[48] Even though United Kingdom is no longer a European Union member State, this Charter maintains its relevance according to a comparative perspective (Ramshaw, Adam. 2020. What Could Have Been And May Yet Still Be: Brexit, the Charter of Fundamental Rights of the European Union and the Right to Have Rights, *European Law Review* (2): 824-839.

[49] Pistorio, Giovanna. 2009. Dignità Umana. In *La Carta dei diritti dell'Unione Europea*. eds. Bisogni, Giacinto, Bronzini, Giuseppe, and Piccone Valeria, 39-50. Taranto: Chimienti.

[50] Losanno, Antonella. 2003. Per un riequilibrio tra la brevettabilità di elementi isolati del corpo umano e la tutela dei diritti fondamentali della persona umana, *Diritto Ecclesiastico*(2): 170-184.

European Union institutions and its Member States[51], on the other hand, the fulfilment of this aim is not easy to identify, since human dignity consists of an indeterminate concept, which cannot be ex-ante predetermined in its absolute meaning. Human dignity protection can be identified after its contextualization in an historical time, a determined territory, and towards specific subjects.[52] Indeed, the task of filling the vague concept of dignity with content is up to the courts and their case law.[53]

The Charter of Fundamental Rights of the European Union has strict margins of interpretation on dignity, which is abused every time human personality is exploited to obtain a purpose or an advantage. Under this perspective, the protection of human dignity guaranteed by Article no. 1 represents a significant obstacle to unlimited freedom of scientific research, against the background of contrast between dignity and liberty, which opposes the European vision of kantian roots of dignity, incorporated in the EU Charter, to the Anglo-American preference for freedom of research.[54] Furthermore, Article 1 of the EU Charter aims to limit persistence of therapeutic treatments, and scientific experiments that would not bring a significant advantage to those who are subjected to them, in particular minors.

Article 2 of the Charter of Fundamental Rights of the European Union has a similar importance, since it recognizes the right to life in very simple terms: "*(E)veryone has the right to life*". Scholars' interpretation of this provision seems oriented in the sense of acknowledging the individual's right to conservation,[55] or preservation, of life, which consists in a positive obligation of the State that must be "appreciated in its measure and being reasonable."[56] This links with the aforementioned article 1, according to the interpretation

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[51] Chalmers, Don, and Ida Ryuichi. 2007. On the International Aspects of Human Dignity, in *Perspective on Human Dignity*, ed. Jeff Malpas and Norelle Lickiss. 157-168. Dordrecht: Springer.

[52] Pistorio, Giovanna, cit.

[53] Pistorio, Giovanna, cit.

[54] Whitman, James. 2004. The Two Western Cultures of Privacy: Dignity versus Liberty. *Yale Law Journal* (113): 1152-1221.

[55] Meoli, Chiara. 2009. Diritto alla Vita. In *Carta dei diritti dell'Unione Europea*, cit.

[56] Lettieri, Nicola. 2009. L'art. 2 della Convenzione dei diritti umani sul diritto alla vita, Giurisprudenza di Merito (09): 2312-2329.

developed by the ECtHR. Therefore, there would be an obligation of the State to safeguard the life of an individual by providing him/her with the same medical care as is guaranteed to all members of the community.

Article 3 enhances the right of each person to self-determination, regarding both his/her own body and psyche, as personal fulfilment in the full and absolute sense, regardless of the factual circumstances that may hinder it.[57] When the manifestation of informed consent refers to a minor, Article no 3.2 deals with the relationship between law and biotechnology and concerns contents already governed by the aforementioned article 17 of the Oviedo Convention.

The combined articles 21 (Non-discrimination) and 24 (Rights of the child) must be read in the light of article 8 (Protection of personal data) of the EU Charter. The discipline organized as such tries to reconcile one of the most complex paradoxes of contemporary medicine which uses advanced scientific research. It refers to "an excessive loss of the degree of autonomy of the person, following the unjustified intrusions of others"[58] caused by the new and disproportionate dependence of the human body on scientific and technological evolution, with the consequent compression of individual fundamental rights.

The delicacy and specificity of paediatric experimentation, especially if carried out on newborn patients, are highlighted by European Union law, which establishes that paediatric research must be conducted solely to respond to the therapeutic needs of newborns,[59] and under the supervision of the European Medicines Agency,[60] in consideration of the small number of candidates and

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[57] Patrone, Ignazio. 2009. Diritto all'integrità della persona. In *La Carta dei diritti dell'Unione Europea*, cit.; Zatti, Paolo. 2008. Rapporto medico-paziente e "integrità" della persona. *Nuova Giurisprudenza Civile Commentata* 12(2): 403-409.

[58] Chieffi, Lorenzo. 2010. Analisi genetica e tutela del diritto alla riservatezza. Il bilanciamento tra il diritto di conoscere e quello di ignorare le proprie informazioni biologiche. In *Studi Atripaldi*, 853-882. Napoli; Jovene.

[59] Whereas no. 13 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004.

[60] CJEU, 4 December 2011. Nycomed Danmark ApS v European Medicines Agency (EMA). Case T-52/09.

the number of paediatric trials carried out, despite their increase following the entry into force of EU Regulation no. 1901/2006[61] and of the fact that they still remain linked to the development of pharmacological therapies for adults.[62]

C. The European Court of Human Rights case law

The European Court of Human Rights (hereinafter ECtHR) case law has few cases of relevance; under a general perspective, one of the most important is Hristozov v. Bulgaria,[63] according to which hospitals must adopt appropriate measures for the protection of their patients (§108), within an appropriate legal framework promoted by the State, given that such treatments are subjected to precise regulation of European origin, both conventional and of the European Union laws. The seminal point of this case regarded the use of unauthorised medicinal products outside clinical trials for certain patients, in particular for those who are terminally ill. From this perspective, could the curtailment of the patient's choice of medical treatment be analysed as an interference with his/her right to respect his/her private life? What is the limit to the right of choice on medical self-determination? Could the patient alone decide to receive "compassionate use" of an unauthorised drug or therapy? And regarding infants, how should this alleged "right of choice" be managed?

The ECtHR noted that the balance between the public interest in regulating the access to experimental products for seriously ill patients needs checks to protect them, given both their vulnerability and the lack of clear data on the potential risks of these "experimental treatments" or "compassionate care". These interests are related to the rights guaranteed under Articles 2,

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[61] Report from the Commission to the European Parliament and the Council better medicines for children — from concept to reality general report on experience acquired as a result of the application of Regulation (EC) no 1901/2006 on medicinal products for paediatric use. 2013. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013DC0443 (last accessed on 7 December 2021).

[62] Report, cit.

[63] ECtHR, Hristozov and others v. Bulgaria. The case concerned the Bulgarian authorities' refusal to allow nine terminally-ill cancer patients access to an unauthorised experimental anti-cancer drug which is not authorised in any country but is tollerated in some other countries for "compassionate use". The Court for the first time examined the issue of access for terminally ill patients to unauthorised medicine.

(right to life), 3 (prohibition of inhuman or degrading treatment), and 8 (protection of private life) of the ECHR. This could balance the patients' interest and "*touches upon complex ethical and risk-assessment issues, against a background of fast-moving medical and scientific developments.*"[64]

In this perspective, the ECtHR affirms that the current trend among the Contracting States allows, under certain exceptional conditions, the use of unauthorised medicinal products. In this sense, the ECtHR affirms that the Contracting States have a wide margin of appreciation, "*especially as regards the detailed rules it lays down with a view to achieving a balance between competing public and private interests.*"[65] The ECtHR affirms that "*it is not for an international court to determine in place of the competent national authorities the acceptable level of risk in such circumstances.*"[66] This is the relevant principle of the ECtHR in this matter:[67] it would therefore not be the task of an international judge to take the place of the competent national authorities in determining the acceptable risk for patients who intend to access compassionate care in the case of experimental therapy, the effectiveness of which has not yet been proved. Furthermore, the national authorities' decision on undergoing clinical trials must be transparent and principal investigators cannot invoke privacy protection to refuse to allow access to the materials on which the research is carried out.[68]

3. THE PROTECTION OF THE BEST INTEREST OF THE CHILD AND THE EXPRESSION OF MEDICAL CONSENT FOR CHILDREN IN ENGLISH LAW

The English law focuses on the evaluation of the child's "best interest". According to §1 of the Children Act 1989 the child welfare paradigm must be

[64] ECtHR, Hristozov and others v. Bulgaria, §122.
[65] ECtHR, Hristozov and others v. Bulgaria, §124.
[66] ECtHR, Hristozov and others v. Bulgaria, cit.
[67] ECtHR, Durisotto v. Italy, cit.
[68] ECtHR, 3 April 2012, Gillberg v. Sweden, app. no. 41723/06.

taken into consideration by domestic courts in case of matters relating to the child, his or her education and property. Indeed, the minor is considered the holder of rights, while the adult (even if this were the parent) of privileges only. In this perspective, the intervention of the State in evaluating the relationship between the rights (of the minor) and the privileges (of the adult) becomes justified.[69]

English common law favours the protection of the best interest and welfare of the child over the conflicting ones of adults, even regards (and to the detriment) of the parents.[70] Therefore, this becomes crucial in resolving the conflict between the positions of adults and minors in favour of the latter. Among scholars, there are those who have considered this approach as a separation, in the interests of incompetent and incapacitated individuals (such as children, or the sick and disabled), from the point of view of their guardians.[71]

For this reason, in the common law perspective, the position of the minor and that of his/her parents (or guardians) is clearly distinct. Indeed, §1 of the above-mentioned Children Act 1989 recognizes an autonomous legal position of minors with respect to their parents and evaluates their welfare and best interest independently from that of the adults involved, even the parents themselves, through an independent authority set up for this purpose.

This is the Children and Family Court Advisory and Support Service (hereinafter CAFCASS).[72] This independent authority takes on the role of

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[69] Ryznar, Margaret. (2007). Adult Rights as the Achilles'Heel of the Best Interest Standard: Lessons in Family Law from across the Pond, *Notre Dame Law Review* (82)4: 1649-1678.

[70] Ryznar Margaret, cit.

[71] Lamarque, Elisabetta, cit.

[72] It is established by §11 del Criminal Justice and Court Services Act 2000. CAFCASS's 'primary aim is to safeguard and promote the welfare of children subject to family court proceedings. A primary function of this role is to represent children's voices, usually by consulting with a child and presenting their views within the Sect. 7 (Children Act 1989) report prepared for the family courts (Macdonald, Gillian. 2017. Hearing children's voices? Including children's perspectives on their experiences of domestic violence in welfare reports prepared for the English courts in private family law proceedings, *Child Abuse & Neglect* (65):1 1-13). §12 affirms «(1)In respect of family proceedings in which the welfare of children is or may be in question, it is a function of the Service to—(a)safeguard and promote the welfare of the children, (b)give advice to any court about any application made to it in such proceedings, (c)make provision for the children to be represented in such proceedings, (d)provide information, advice and other support for the children and their families)» (Bilson,

guardian, that is the trustee of the minor in proceedings, and looks after children's interests before the courts in litigation concerning separation or divorce of parents, adoptions, decisions concerning the psycho-physical integrity of their person or their health conditions, representing children's voice and interests. CAFCASS allows the legal position of the minor to be clearly distinguished from that of his/her parents, making this role free from conflicts of interest whatever their origin, emotional or economic, as well as valuing the autonomy of the minor with respect to his/her (inevitable) dependence on adults.[73] This aspect is of significant importance in the field of paediatric clinical trials, where medical evaluation of the research procedure is essential, since the experiment itself is the reason for the manifestation or the denial of consent to the clinical trial, despite the presence of further elements (emotional, moral, legal) that should be considered in making the decision about the involvement of the child in it.[74]

However, British scholars have expressed doubts about this approach since it could risk disaggregating the rights of the child, which should be preserved by coordinating the discipline of the Children Act 1989 with the Human Rights Act 1998.[75] Indeed, the Human Rights Act 1998 introduced a more utilitarian approach to this criterion, albeit without abandoning the basic path,[76] but giving greater importance to the position of adults, especially in the case of parents, as bearers of rights pursuant to Article no. 8 ECHR.[77] In addition to scholars' opinion, this argument has the support of courts, which assert that the judge must interpret the provisions of the Children Act 1989 with respect

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Andy, and White, Sue. 2005. Representing children's views and best interests in court: an international comparison. *Child Abuse Review* (14):4 220-239; Masson, Judith. 2010. Judging the Children Act 1989: Courts and the administration of family justice. *Journal of Children's Services* 5(2): 52-59).

[73] Lamarque, Elisabetta, cit.

[74] Venturi, Filippo. 2017. Il principio dei best interests of the child nel caso Gard, tra paternalismo, autonomia e indeterminatezza. *Federalismi-Focus Human Rights* 3: 1-15.

[75] Ferguson, Lucinda. 2013. Not merely rights for children but children's rights: The theory gap and the assumption of the importance of children's rights*, International Journal of Children's Rights* (21): 177-208.

[76] Choudhry, Shazia and Fenwick Helen. 2005. Taking the Rights of Parents and Children Seriously: Confronting the Welfare Principle under the Human Rights Act*. Oxford Journal of Legal Studies*, 25(3): 453–492.

[77] Ryznar, Margaret, cit.

for the mother, father and each child, even if the rights of the child take priority over those of their parents.[78]

Particularly relevant is the precedent In Re King[79]: establishing that the law should give priority to the motives of parents who intend to submit their child to a certain unapproved medical treatment, while the control of the judicial authority should be limited only to the case where it is probable that the child suffers "significant harm" due to such treatment.[80] The Court of Appeal rejected this argument stating that the relevant decision parameter is the protection of the best interest of the child, not that of "significant harm", and that the object of the case was the withdrawal of life support proposed by the physicians. The judge therefore had to assess whether the extension of such treatment constituted the best interest of the child. The Court of Appeal agreed with the first instance judge that the continuation of the minor's suffering was not in his/her interest.[81]

4. RECENT AND RELEVANT CASES IN COMMON LAW

On this point, many doubts have emerged about the management of relations between parents, medical and health staff, and public authorities, as well as about the application of legal rules in relation to the cases of Charlie

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[78] (M (Children) [2013] EWCA Civ 1147, 20 September 2013; Zoumbas v Secretary of State for the Home Department [2013] UKSC 74 (27 November 2013).

[79] King (A Child), Re [2014] EWHC 2964 (Fam) (8 September 2014).

[80] The case involved a five-year-old boy who had a brain tumor removed in an English hospital. After the surgery, the doctors intended to subject him to cycles of conventional chemotherapy, as established by a medical protocol, however the parents opposed asking that he be given a different type of chemotherapy cycles (proton chemotherapy) which, however, was not available in the United Kingdom. The British health system authorized treatments abroad for this method for the purpose of reimbursing health costs, but not in the case of the pathology for which the child had been operated on. Faced with this situation, the parents took the child abroad, without the authorization of the health staff, first to Spain, where the baby was born, then to Prague, where the aforementioned treatment was administered. A European arrest warrant was issued against the parents, accused of endangering their child's health (King (A Child), Re [2014] EWHC 2964 (Fam).

[81] [Great Ormond Street Hospital v Yates & O rs [2017] EWHC 972 (Fam) (11 April 2017); Yates & Anor v Great Ormond Street Hospital For Children NHS Foundation Trust & Anor (Rev 1) [2017] EWCA Civ 410 (23.5.2017; Alder Hey Children's NHS Foundation Trust v Evans & Anor [2018] EWHC 308 (Fam) (20 February 2018)].

Gard,[82] Alfie Evans,[83] Isaiah Haastrup,[84] Tafida Reqeeb,[85] and Alta Fixsler,[86] the English infants suffering from incurable pathologies, which had caused a slow and unstoppable decay of their vital functions.[87] The parents had always refused to accept what seemed to be the inescapable fate of their children.

Tafida Reqeeb's and Alta Fixsler's cases move the debate a step further away from the role of science and medicine, but these cases remain relevant to this topic since they bring out clearly the influence of religious belief, in letting a new and different contradiction emerge with regard to the role of parents in protecting the best interests of their child and the acceptance of scientific findings in the treatment of infants by the parents themselves.

A. Charlie Gard's case

From a double point of view, the Gard affair presents extra-juridical aspects that undoubtedly have – or risk to have - a legal impact: on the one hand the administration of "compassionate" treatment to very young children, and, on the other hand, the pressure of public opinion through social networks against the official medicine.

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[82] ECtHR, 28 June 2017, Gard and others v. United Kingdom, app. n. 39793/17.

[83] ECtHR, 23 April 2018, Evans v. the United Kingdom app. n. 18770/18.

[84] Kings College Hospital NHS Foundation Trust v Haastrup (Withdrawal of Medical Treatment) [2018] EWHC 127 (Fam) (29 January 2018), ([2018] 2 FLR 1028, [2018] EWHC 127 (Fam).

[85] Raqeeb, R (On the Application Of) v Begum & Anor [2019] EWHC 2976 (Admin) (11 November 2019) ([2019] EWHC 2976); Barts NHS Foundation Trust v Raqeeb & Ors [2019] EWHC 2530 (Fam) (03 October 2019) ([2019] EWHC 2530 (Fam); Raqeeb v Barts NHS Foundation Trust [2019] EWHC 2531 (Admin) (03 October 2019) ([2019] EWHC 2531 (Admin); Raqeeb v Barts Health NHS Trust (Costs) [2019] EWHC 3322 (Fam) (03 December 2019) ([2019] EWHC 3322 (Fam); Raqeeb v Barts Health NHS Trust (Costs) [2019] EWHC 3320 (Admin) (03 December 2019); ([2019] EWHC 3320 (Admin); From England and Wales High Court (Administrative Court) Decisions; 65 KB).

[86] Manchester University NHS Foundation Trust v Fixsler & Ors [2021] EWHC 1426 (Fam) (28 May 2021).

[87] Wilkinson, Dominic, and Savulescu, Julian. 2018. Alfie Evans and Charlie Gard—should the law change? *British Medical Journal,* 361.

On the first point, a common problem concerns the access to a treatment not yet validated due to the high costs or the low number of patients.[88] There are difficult questions to answer here:

1. what is the ethical value of administering a treatment in the name of the care of a patient certain of dying within a short time;

2. what are the margins of freedom for the patient to dispose of his/her own body;

3. what are the limits of the precautionary principle, especially in relation to the manifestation of consent for children not yet able to express themselves.

These questions introduce the balance between the benefits and risks of access to so-called "compassionate care" which should be reasonably authorized in the presence of a minimum set of scientific evidence (such as hyper-specialized literature).[89]

The main point concerns whether it is appropriate to talk of informed consent with regard to a treatment if its scientific assumptions, methods of administration and possible side effects are not known, considering the fact that informed medical consent assumes legal relevance in the relationship between patient and physician or scientist.[90] In this regard, in the case of treatments not yet adequately tested, "*the informed consent (...) only in part could be a declaration of personal risk assumption*",[91] which, however, risks turning patients into guinea pigs, endorsing practices that are neither justifiable

[88] Comitato Nazionale per la Bioetica (Italian Bioethic National Committee). 2015. Cura del caso singolo e trattamenti non validati (c.d. "uso compassionevole"). Rome: Presidenza del Consiglio dei Ministri, www.governo.it/bioetica (last accessed on 7 December 2021).

[89] Comitato Nazionale di Bioetica, cit.

[90] Rossi, Stefano. 2012. Consenso informato. Digesto delle discipline privatistiche. Appendice di aggiornamento VII. ed. Rodolfo Sacco, Torino: UTET 177 ss.

[91] Comitato Nazionale di Bioetica, cit.

from a legal point of view, nor from a bioethical one.[92] Is this acceptable for a very young child like Charlie?

The request for treatment by the patient alone must not be binding for physicians, and patients wishing to access this type of therapy must be guaranteed full explanations of the possible dangers they could face. Conflicts of interest must be reported by the person administering the unapproved treatment, and it must not be kept secret. The limit (cost) of the treatment must be borne by the producers, while control of the administration must be carried out by the responsible public structures. Only when all of these points are met can compassionate treatment be considered ethically lawful and fall under the right to health. Nevertheless, from the facts made public in the course of the case, it is clear that the treatment requested by the parents could not be applied to Charlie.

On this point, the importance of the relationship between doctors and parents emerges in protecting the best interest of the child, like Charlie. His story has shown that the presence of CAFCASS can make the relationship between the parties involved more fragile.

Charlie's parents appealed to the ECtHR about their son's life support withdrawal, trying to stop it. The Court observed that although Charlie Gard could not express his views personally, he was assisted by an independent guardian, prepared for this purpose in court and who looked after his interests. In addition, the opinion of the medical staff involved (experts, paediatricians, nurses) in the case had been heard and the applicant parents were also invited to present their expert doctors. In addition, the court gave the American expert the opportunity to discuss his professional view on the problem. Therefore, the second point was also satisfied, while the third issue was fulfilled since the GOSH, faced with the doubt as to which was the best interest of the child, presented a specific application before the Court under English law.

In fact, in light of the lack of shared consensus on the access to experimental medical treatments for terminal patients, the margin of

[92] Comitato Nazionale di Bioetica, cit.

appreciation was wide (as recalled in the Hristozov case), especially in light of the fact that the case in question concerned delicate moral and ethical issues. Therefore, the Strasbourg Court stressed that the British legal landscape was appropriate and the health and judicial authorities had operated within the margin of appreciation in this sphere, with not disproportionate, but meticulous measures taken after taking into account evidence produced by first-rate experts, reviewed by three degrees of judgment with clear and reasoned legal reasoning, therefore no interference was configurable.[93]

In this specific case, Charlie's parents had turned to an American specialist who had made himself available for the elaboration of a specific protocol for the experimentation of a treatment that could potentially improve Charlie's health conditions, prolonging the expectation and the quality of his life. Nevertheless, this protocol had never been tested, while for the purposes of the experimentation, Charlie would have had to be transferred to the United States. To this end, a vast fundraising campaign was organized, representing a possible risk of conflict of interest with the promoters of the experiment themselves.[94]

With the decision of the High Court of Justice of 24 July 2017, Justice Francis held that the parents renounce the transfer of their child to the United States and the affair should be closed with the administration of palliative care and the suspension of artificial ventilation in a special hospice. Doctors and judges relied on medical evidence and not on the basis of biased or misinformed

[93] The ECtHR stated a similar conclusion in the Parfitt case: the applicant's five-year old child suffered from Acute Necrotising Encephalopathy and she lives in a permanent vegetative state with no prospect of improvement. On 8 January 2021 the High Court made a declaration to the effect that it would not be unlawful for the hospital staff to withdraw life support treatments to the applicant's daughter. On 19 March 2021 the Court of Appeal dismissed the mother's appeal, considering that the first instance court took its decision according to the best interest of the child. On 1 April 2021 the Supreme Court of United Kingdom refused permission to appeal. After that, the ECtHR considered that the decisions of the domestic courts had not been arbitrary. At both levels of jurisdiction the courts' examination had been meticulous and detailed; all persons concerned had been separately represented in the proceedings; extensive and high-quality expert evidence had been heard; weight had been accorded to all the arguments raised; and the courts had given clear and extensive reasoning to support their conclusions The applicant's complaints were therefore declared inadmissible (ECtHR, 12 April 2021, Parfitt v. United Kingdom, app. n. 18533/21).

[94] Cave, Emma, and Nottingham, Emma. 2018. Who Knows Best (Interests)? The Case of Charlie Gard. *Medical Law Review* (26)3: 500–513 504 ss.

opinions also disseminated through social media: "*The world of social media doubtless has very many benefits but one of its pitfalls, I suggest, is that when cases such as this go viral, the watching world feels entitled to express opinions, whether or not they are evidence-based"*.[95]

This context thus highlighted the need for a "personalized medicine", due to the greater attention and accessibility to scientific information of patients and their families through access to information available online[96] and to specialized research in scientific literature such as Google Scholar or PubMed, but without the skills for an appropriate scientific analysis. At the same time, it is based on an absolutist and libertarian application of the principle of self-determination, which almost imposes itself on the healthcare practitioner;[97] as well as on the possibility of patients and their families to combine their (alleged) skills, ensured by social networks,[98] in order to mutually support them in common claims.[99] On the other hand, it is observable that the time required by rigorous scientific experimentation is not compatible with patients' needs, since their life expectation is shorter than time needed to fulfil a proper clinical trial.[100]

B. Alfie Evans' case

The Alfie Evans case presented similar critical issues. Alfie was a child of just over a year, suffering from irreversible disease: also in this case the English court had prohibited his transfer abroad, to Italy, as requested by his parents,

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[95] Gard (A Child), Re [2017] EWHC 1909 (Fam) (24 July 2017), §11.

[96] Dreger, Alice. 2015. *Galileo's Middle Finger*, 1st edition, 257. New York: Penguin.

[97] Scalera, Antonio. 2014. Il caso Stamina tra diritto e scienza. Nuova Giurisprudenza Civile Commentata (2)2: 75-84.

[98] Tieman, Jeff. 2012. The facebook frontier: compelling social media can transform health dialogue. Health Prog. (93)2: 82-83; McKee, Rebecca. 2013. Ethical issues in using social media for health and health care research *Health Policy*110(2-3): 298-301.

[99] Comitato Nazionale di Bioetica, cit.

[100] Comitato Nazionale di Bioetica, cit.

after the granting of Italian citizenship by the Italian government for administering life support to him in a hospital run by the Vatican.[101]

In both Gard and Evans cases an apparent contradiction emerged: on the one hand, the shared sensitivity towards the demand for "death with dignity" was outlined with increasing emphasis. In this perspective, it is debated whether it is possible to recognize the right of a newborn child to be helped to die as an extreme expression of the right not to suffer. It is a discussion with broad ethical, political and religious implications, which undoubtedly had an effect on public opinion, also following the secularization of contemporary life and the acknowledgment of the non-omnipotence of medicine, despite the intrusiveness of technology in the artificial lengthening of human life.[102] On the other hand, there is a greater collectively shared reactivity, relating to the rejection of the death of a child, today considered "peculiarly painful" and therefore unacceptable.[103]

This emotional sensation manifested the presence of a contradiction in the circumstance that in the face of an incurable and irreversible disease, which has caused such serious damage as "*to be irrecoverable even for Italian medicine*",[104] there can be no alternative practicable when the vital treatments are suspended, while at the same time parents asked for support for the maintenance of their child's life, regardless of the relief they might have obtained.[105]

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[101] Lamarque, Elisabetta. (2018). *Alfie Evans cittadino italiano. Bene, certamente. Ma perché solo lui? BioLaw Journal – Rivista di BioDiritto* 2: 42., 42.

[102] As a British scholar said: "*the continuation of life is not an absolute good*" (Wicks, Elizabeth. 2016. *The State and the Body. Legal Regulation of Bodily Autonomy*, 1st edition, 78. Oxford-Portland: Hart.

[103] Vovelle, Michel. 2000. La Morte e l'Occidente 2nd edition. VIII, Roma-Bari: Laterza.

[104] Adamo, Ugo *Cultura della vita e cultura della morte: interrogativi sul caso del piccolo Alfie Evans*, www.lacostituzione.info (last accessed on 7 December 2021).

[105] Evans & Anor v Alder Hey Children's NHS Foundation Trust & Anor (Rev 1) [2018] EWCA Civ 984 (25 April 2018) §10 e ss.

C. Isaiah Haastrup's case

Shortly after the Gard and Evans cases Justice MacDonald, of the Family Court Division of the High Court of Justice,[106] dealt with a case concerning an 11-month-old child in a persistent vegetative state: Isaiah Haastrup was an anoxic child born through an emergency caesarean delivery, as he was stuck in the maternal abdominal cavity, causing the uterus to rupture. Doctors had attempted to resuscitate him, but he had not been out of the ICU since his birth, nor had there been any improvement in his condition. Kings College Hospital filed for a judicial statement that it was no longer in his interest to give him vital treatment, but that he should only receive palliative care. The dispute over the continuation of vital treatment was pitted between parents and doctors, while the representative of the CAFCASS supported the latter's position.

For the purposes of deciding in cases where there is no agreement between the parents and the health professionals, the judge is not strictly required to follow the clinical evaluation of the doctors, but his assessment of the best interests of the child should be based on the medical evidence available. Although there is a "strong presumption" in favour of the preservation of life, this is not irrefutable. In these cases, how is it possible to protect the best interest of the child if two opposite alternatives are placed before the judge? the suspension of the therapies, as requested by the health professionals, and the continuation of the same, as desired by the parents? How do they see in this context the circumstances that the child is suffering or that his health conditions may improve?

Justice MacDonald's reasoning started from an interesting point of view regarding the points in common of the Haastrup and Raqeeb cases, albeit with opposite results in the conclusions. This starting point concerns "*the assumed point of view of child"*[107]: in particular, his attitude towards the life-saving treatment to which he is subjected, if his condition causes him pain and if the child is able to perceive it. Given his very young age, he was eight months old

[106] Kings College Hospital NHS Foundation Trust v Haastrup (Withdrawal of Medical Treatment) [2018] EWHC 127 (Fam).
[107] [2018] EWHC 127 (Fam), §§ 69 and 100.

at the time of judgment, he was unable to understand his parents' opinions, attitudes, and beliefs. Furthermore, the medical treatment that kept him alive allowed him a condition of minimal consciousness, with no prospect of improvement or recovery, but with the possibility of worsening by incurring infection. In the light of this, one might wonder what Isaiah's attitude to survival was and his possible perception of pain.

D. Tafida Raqueeb's case.

Tafida Raqeeb was a five-year-old girl, struck by the rupture of a brain vein caused by an asymptomatic congenital malformation. Urgently hospitalized at King's College Hospital in London, the little girl underwent surgery to reduce the very serious brain damage. Later, the little girl was transferred to the paediatric intensive care unit at the same hospital for two months and then to the Royal London Hospital. The story of Tafida differs in two circumstances: first, by the fact that her conditions are serious, but not such as to prevent a survival that no one is able to predict in terms of duration; second, the girl had already shown a marked propensity for religion, even though this circumstance was held in exaggerated consideration for the case of a five-year-old girl.[108] In any case, Justice MacDonald noted that Tafida, despite her very young age, embracing the teachings of her practising Muslim parents, held in high regard the protection of all forms of life.[109]

Already the doctors of King's College Hospital had warned the parents of the improbability of her survival and that Tafida would remain severely disabled, in need of vital treatment and with a life expectancy limited to a few months. Doctors advised parents, observant Muslims, to go to a palliative care centre. Instead, the parents refused to suspend life-saving treatment, making it clear that they actively wanted to treat her. In this period Tafida's brain, despite being in disastrous conditions, showed signs of activity. Two important facts

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[108] Cave Emma, Brierley Joe, and David Archard. 2020. Making Decisions for Children-Accommodating Parental Choice in Best Interests Determinations: Barts Health NHS Trust v Raqeeb [2019] EWHC 2530 (Fam). Raqeeb and Barts Health NHS Trust [2019] EWHC 2531 (Admin). Medical Law Review 28(1): 183-196.

[109] To prove this assumption, the parents affirm that the daughter *"demonstrated herself to greatly value all life, reiterating a story of Tafida becoming upset at the death of a ladybird and of a goldfish, and of Tafida's gentle, accepting and non-judgmental approach to another child with serious disabilities*."

emerged here: on the one hand, in compliance with the absolute opposition of the parents, the medical personnel would not have proceeded with the interruption of vital treatment, even if this had been legally possible; on the other hand, the parents had verified and obtained the availability of the Gaslini hospital in Genoa to welcome and treat Tafida if they had borne the costs of the transfer and treatment.

These circumstances affected the *thema decidendum*: it was no longer a question of authorizing the suspension of vital treatments (a circumstance already excluded by the doctors' declaration regarding respect for the religious beliefs of the parents), but whether or not the transfer of Tafida to Italy met to her best interest. Therefore, two petitions were pending before Justice MacDonald: a) that of the parents, intending to transfer their daughter to Gaslini in Genoa (given that Italian law does not allow the active suspension of the so-called "life-saving" treatments, as Tafida is not "cerebrally dead"); and b) that of the Barts Health NHS Trust (the body that manages the Royal London Hospital, where Tafida was hospitalized at the time of the case), which requested the judge to issue an order pursuant to Sect. 8 of the Children Act 1989, which allowed the interruption of vital treatment to the child. This distinction between the position of doctors, respectful of the will of the family, and the Barts Health NHS Trust, which maintained the request for suspension of treatment, was relevant as it is necessary to obtain prior authorization from the NHS[110] for reimbursement by the service for a series of specialized treatments carried out abroad or within the European Union.

E. Alta Fixsler's case

Alta was born premature, and suffered a severe hypoxic ischemic brain injury during her birth in 2018.[111] The severity of her injury is not doubted either by her parents or by the medical staff, which are aware that she could die within

[110] NHS Choices: revised information for patients, https://www.england.nhs.uk/publication/nhs-choices-revised-information-for-patients (last accessed on 7 December 2021).
[111] [2021] EWHC 1426 (Fam), cit.

a couple of years. The child is mechanically fed and ventilated, she is not aware and does not interact with the environment around her: Alta lives in a "*state of perpetual darkness and silence.*"[112] The main question concerns whether the child experiences sensations, especially pain, given that there is no improvement after medical treatment, and consequently if it is in her best interest to undertake palliative care which will lead to the termination of life support.

The parents, both Chassidic Israeli Jews, supported by rabbinic opinions, refused to interrupt their daughter's care, as it was against religious obligations "*to be involved in bringing death closer*", and ask to take her to Israel in order to bring her closer to the Holy Land in the moment of passing away. Although a very long and argued opinion, Justice McDonald's decision is linear: the continuation of life support could not represent the best interest of the child since the pain suffered by her, which does not show that she is even able to react to it or perceive its intensity, represents an extension of a suffering that harms her dignity. Alma's clinical conditions confine her to a hospital room without her being able to consciously realize what is happening to her and what happens around her.

The judge explicitly compares this case with Raqeeb'one, because the evaluation of the prospective of Alta should assume that she would share the values of her parents, her brother and her wider family and community, but her condition would never allow her to share those values or be part of family life or of the community. So, the issue pertaining to this case is how to balance the presumption in favour of preserving life with the need to alleviate suffering. Justice MacDonald referred to an ancient American Supreme Court case (1944) 321 US 158 according to which "*the parent's rights to manifest their religion are necessarily circumscribed by the interest of the child. The judge affirmed that it is not religious law that governs the decision in this case, but the secular law of this jurisdiction* ".

In Alta's case Justice McDonald distinguishes his position from the Raqeeb case, getting closer to the principle stated in Haastrup: the infant had

[112] [2021] EWHC 1426 (Fam), cit., §101.

not shown that she was able to be present and interact, and the treatments did not offer any possibility of improvement. So, for respecting the child's dignity the judge allows the administration of the palliative care, and the detachment of life support.

5. THE ITALIAN LEGAL DISPUTE ON A PSEUDO-THERAPY: THE "STAMINA" CASE

In Italy there was a long legal dispute involving infants and regarding the access to a not properly tested medical treatment based on mesenchymal stem cells known as "Stamina", which turned out to be fraudulent.[113]

The Stamina Foundation was a private organisation created by Mr Davide Vannoni, who was neither a doctor nor a scientist, but a communications expert. Stamina Foundation argued "*that the stem cells collected from human bone marrow can be transformed into neural cells by exposure to retinoic acid, an important molecule in embryonic development.*"[114]

According to this 'treatment', which turned out to be fraudulent, these stem cells could improve severe conditions of muscular dystrophy or spinal atrophy, despite the fact that there were no published scientific studies under double-blind peer review to prove this. However, this treatment gained public attention and political support, which made it possible for it to be administered in public hospitals on the order of civil courts.[115]

This complex vicissitude showed two relevant aspects: on the one hand, the high expectation of public opinion about medical therapies for degenerative

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[113] Piccinni, Mariassunta. 2014. Tutela della salute versus libertà di cura? Il caso Stamina nella lente deformante dell'urgenza. *Politica del Diritto* (4):607-638; Capocci, Mauro and Corbellini, Gilberto. 2014. Le cellule della speranza. Il caso Stamina tra inganno e scienza. 1st edition, Turin: Codice.

[114] Cattaneo, Elena., Corbellini, Gilberto. Stem cells: Taking a stand against pseudoscience. *Nature* 510, 333–335 (2014). https://doi.org/10.1038/510333a.

[115] Zettler, Patricia J. "Compassionate use of experimental therapies: who should decide?." *EMBO molecular medicine* vol. 7,10 (2015): 1248-50. doi:10.15252/emmm.201505262.

and incurable diseases, in the case of newborn or very young children.[116] On the other hand, the fact that the case was widely publicized by tv shows and mass media,[117] emphasized emotional aspects and minimized the negative side effects due to the harmfulness of a pseudo-medical treatment."[118] Under this point of view, there was a clash between the civil courts case law that granted the applicants access to a mysterious and untested treatment,[119] and the Turin criminal court which sanctioned the promoters of this fraudulent treatment.[120] This contrast between courts shook public opinion: how did it happen?

A possible answer refers to the improper use of the term "compassionate" (*compassionevole*) referred to a medical treatment.[121] Although this term is contained in several court decisions,[122] it did not exist in the relevant law text in force at that time, namely the Ministerial Decree 5 December 2006 (hereinafter "DM Turco-Fazio"), later repealed by the subsequent Ministerial Decree 16 January 2015. The "DM Turco-Fazio" regulated "*the treatments of somatic or gene therapies that can be used on individual patients in the absence of a valid therapeutic alternative, in cases of urgency and emergency, which place the patient in danger of life or serious damage to health, as well as in cases of severe disease with rapid progression, in presence of scientific evidence published in accredited scientific journals.*"[123]

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[116] Vovelle, Michel, cit.

[117] Cattaneo Elena, Corbellini, Gilberto, and De Luca, Michele. 2014. Sul caso Stamina l'informazione-spettacolo è stata irresponsabile, La Stampa. It should be noted that the Italian National Communication Authority (AGCOM) did not find any violations of the regulation in force at the time: "even in cases in which the emphasis was more evident, it could be justified by the high social value of this issue". (Senato della Repubblica. 2015. Indagine conoscitiva su origine e sviluppo del cosiddetto caso Stamina, Rome, http://www.senato.it/Leg17/3687?indagine=38. (last accessed on 7 December 2021).

[118] Fasolo, Aldo. 2014. Cellule staminali, embrionali, adulte e riprogrammate lo stato dell'arte. *Scienza e laicità, Quaderni Laici:*21-26.

[119] Veronesi, Paolo. 2015. Al crocevia del "caso Stamina" e dei suoi "problemi costituzionali *Forum di Quaderni Costituzionali*, www.forumcostituzionale.it (last accessed on 7 December 2021).

[120] Giustetti Ottavia, and Ricca Jacopo. 2015. Caso Stamina, ok a patteggiamento per Vannoni, https://torino.repubblica.it/cronaca/2015/03/18/news/caso_stamina_accolto_la_richiesta_di_patteggiamento_di_vannoni_e_andolina-109854055/ (last accessed on 7 December 2021).

[121] Indagine conoscitiva, cit.

[122] Tribunale di Taranto (It.), 24 September 2013.

[123] Indagine conoscitiva, cit.

Likewise, "compassionate care" must be distinguished from "palliative care", whose legislation is not applicable to non-repetitive drugs for advanced therapies, which were governed by the aforementioned Ministerial Decree December 5, 2006 and whose purpose is to "alleviate" the suffering of persons affected by chronic or terminal illnesses.[124] So, why has there been widespread talk of "compassionate care", in the area of terminal or incurable diseases of newborn and infant children? Indeed, the regulation governing the "compassionate use" of experimental drugs is the D.M. May 8, 2003, known as the "Sirchia Decree".[125] In the case of serious danger to the patient's life without an alternative and valid medical treatment, this decree authorized use of a drug still in its II or III experimental phase,[126] therefore without the official authorization to provide such medical treatment to the drug supply chain. Under these circumstances, this drug must be provided free of charge to the patient that expressed his/her specific informed medical consent.[127] The *ratio* behind this discipline concerns the provision of access to the medical last resort through the use of experimental treatments.

Over time, the various ordinances issued on the subject,[128] in many synthetic decisions, the reasons of science were stifled, giving rise to a series of medical prescriptions issued by judges and not by physicians, "*in open contrast to the rulings of the scientific community, and regulatory authorities. This approach created a worrying phenomenon of coercion, especially against doctors enrolled in the public health service, who have had to comply with such 'prescriptions', in contrast with every criterion of 'science and conscience' and of technical regulations*."[129]

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[124] Law 15 March 2010, no. 38.

[125] Pace, Tommaso. 2014. Diritto alla salute o diritto alla speranza? L'accesso al "metodo Stamina" per i pazienti affetti da patologie incurabili. *Nuova Giurisprudenza Civile Commentata* (2): 133-139.

[126] Pace, Tommaso, cit.

[127] Indagine conoscitiva, cit.; Pace, Tommaso, cit.

[128] Nucci, Giulia, Piergiovanni, Daniele, Gabbrielli, Mario, and Benvenuti, Matteo. 2014 Il cosiddetto "metodo Stamina": cronistoria, giurisprudenza ed esperienze casistiche personali. *Rivista Italiana di Medicina Legale* (2): 431-451.

[129] Buzzi, Fabio and Tassi, Giacomo. 2014. La « supremazia » dei giudici, la sudditanza della scienza medica e la cedevolezza della governance amministrativa e politica in materia di trattamenti sanitari impropriamente

On this patchwork of rules, emotions, and sufferings, the misunderstanding about "compassionate care" has been formed. It was not specifically established by the relevant regulations, rather it seems to have been created for this purpose by an imaginative combined interpretation of the two above-mentioned ministerial decrees, even though they were in force in different fields. On the one hand, the so-called “Stamina method” was never subjected to any experimentation (as required by the “Sirchia Decree”) because, as certified by two scientific committees in charge of this purpose, it did not have the minimum requirements to start any clinical trial.[130] On the other hand, the aforementioned method had never been the subject of internationally accredited scientific publications (as required by the "Turco-Fazio" Decree).[131] Moreover, scholars observed that the discipline of the Ministerial Decree "Turco-Fazio" did not even seem to adhere to the European Union rules on the matter. In fact, article 83 Regulation (EC) 31 March 2004, n. 726/2004 gives the Member States of the Union the right, for humanitarian reasons, to make certain drugs not yet authorized available to patients not otherwise curable, "*provided that the drug requested has already been the subject of a request for marketing authorization, or undergoes clinical trials*".[132] However, the issue does not seem to have been addressed in the various ordinances authorizing the use of the so-called “Stamina method”.

Furthermore, the background to this scene provides some issues of great impact on public opinion, such as the distrust of official science, the invasion of the field carried out by many judges in the scientific field, authorizing the administration of the alleged treatment only on the basis of assertions not based on sufficient scientific evidence, the widespread belief that a series of judgments could subvert the scientific evidence.[133] Unlike the juridical reality, science is empirical: it concretely verifies the existence of hypotheses, it does not confine them to mere “minority opinions”, as happens for the legal

qualificati come «compassionevoli»- *Rivista italiana di medicina legale e del diritto in campo sanitario* (2):415-430.

[130] Indagine conoscitiva, cit.

[131] Indagine conoscitiva, cit.

[132] Pace, Tommaso, cit.

[133] Dreger, Alice, cit.

interpretative theories of minor impact. In fact, scientific hypotheses are either verifiable (or verified) or are wrong. Furthermore, a further reflection is considered on the balance of interests between freedom of self-determination of care, which does not integrate the "*right to choose the cure*", with the limited financial resources of public health services.

After this case law experience, the need emerged to reform the discipline on advanced therapies in a more restrictive sense, in order to prevent the repetition of similar legal-scientific contradictions. In this regard, the Ministerial Decree of 16 January 2015 was issued. It is entitled "Provisions regarding medicinal products for advanced therapies prepared on a non-repetitive basis", consisting of 10 articles and abrogating the previous Ministerial Decree of 5 December 2006, "Turco-Fazio", but leaving the "Sirchia Decree" in force. This new ministerial decree establishes the technical specifications for the issue of authorization by the Italian Medicines Agency for the production and use of advanced therapy medicines prepared on a non-repetitive basis, pursuant to art. 3, co 1, lett. F-bis) of Legislative Decree 219/2006 and subsequent amendments. The new Ministerial Decree appears to be much more stringent than the previous discipline, also in the linguistic approach, eliminating any possible misunderstanding on the so-called "Compassionate therapies".

6. THE NEW ITALIAN REGULATION ON MEDICAL INFORMED CONSENT

In 2017, after the Stamina case, the Italian Parliament approved a new law related to the expression of informed medical consent: Law 22 December 2017, No 219. It is entitled "*Regulations on informed consent and advance treatment provisions,*" and regulates both informed consent on medical treatment and the "*Advance Decision to Refuse Treatment*", commonly named "living will". Specifically, Article no. 3 regulates informed consent for minors and incapacitated persons.[134] On the basis of the first paragraph, minors and

[134] Baldini, Gianni. 2019. L. 219/17: minori, incapaci e autodeterminazione terapeutica tra luci e ombre. *Diritto delle successioni e della famiglia.* (1): 7-25; Piccinni, Mariassunta. 2018. Decidere per il paziente: rappresentanza e cura della persona dopo la L. N. 219/2017. *Nuova giurisprudenza civile commentata* (7-8): 118-1128.

incapacitated persons have the right to the "enhancement" of their understanding and decision-making abilities, respecting the rights to life, health, dignity and self-determination of the person. Furthermore, minors and incapacitated persons must receive information on health-related choices, in a manner appropriate to their abilities, in order to enable them to express their wishes. The second paragraph affirms that the informed medical consent regarding minors is expressed (or refused) by parents or guardian, taking into the account the will of the minor, in consideration of his or her age and maturity, having the purpose of their life and psychophysical health protection, fully protecting the dignity of the child in case of conflict between parents.

From a legal perspective, minors' and incapacitated persons' legal position could be overlapped, since they both enjoy legal capacity, the right to life, respect for psycho-physical integrity, health and the best possible quality of life. This means the recognition of "*a basic principle according to which minors and incapacitated people have a right to life and health that cannot be compromised by the decision of those who represent them*:"[135] this sentence appears obvious or apodictic. However, this principle seems to be disappearing since the above-mentioned new legislation does not take into account the fact that the respective situations vary because the degree of awareness and experience of minors and incapacitated persons differs according to the age of the former and the health conditions of the latter. In this regard, only physicians appear to be able to safeguard the protection of the aforementioned rights of these weak subjects, especially in the experimental field since doctors have the appropriate skills to assess the health status of the minor patient and appropriate scientific knowledge on the latest medical-scientific research lines.

This is important from the point of view of the administration of experimental therapies, for which informed consent must be given. It should be noted that, according to this new law, the case of conflict of will between the parents has not been explicitly envisaged, nor has any role been envisaged for the physician who takes care of the child patient. Therefore, it is understood

[135] Gambino, Alberto, Calipari, Maurizio. 2013. http://www.senato.it/application/xmanager/projects/leg17/attachments/documento_evento_procedura_commissione/files/000/005/267/GAMBINO.pdf (last accessed on 7 December 2021).

that the regulations would apply in general (which provides for recourse to the judge for cases of conflict on issues of particular importance for the minor) referred to in Article 316 of the Civil Code*,* relating to the discipline of parental responsibility, to which paragraph 5 of the above-mentioned Article 3 refers.

Although, in a context of unanimous denial of parents, or of the legal representative, the physician could not activate the aforementioned judicial procedure since the physician himself, adhering to the denial, would be exempt from liability pursuant to art. 1, paragraph 6.[136] In this case, there could be a gap in the protection of the best interest of the minor, even though it should be noted that the interpretation of the jurisprudence in ethically sensitive issues is often fragmentary, linked to the specific case and forces the families involved to support the additional costs due to the judicial procedure.

Conclusion

The cases examined in this article present two main points of interest:

a) these cases regard minors suffering from a severe health condition leaving them no hope of recovery or of an autonomous or conscious life;

b) according to the experience of British hospital staff (who cared for these patients), the withdrawal of life support was in accordance with the protection of the best interest of these children. In order to respect the dignity of young patients, it was necessary to follow formal compliance with the procedures established by law. However, the affirmation of this

[136] The physician is required to respect the will expressed by the patient to refuse medical treatment or to renounce it and, consequently, the physician is exempt from civil or criminal liability. The patient cannot demand health treatment contrary to the law, professional ethics or good clinical-care practices; if the patient makes such requests, the doctor has no professional obligation (*Il medico è tenuto a rispettare la volontà espressa dal paziente di rifiutare il trattamento sanitario o di rinunciare al medesimo e, in conseguenza di ciò, è esente da responsabilità civile o penale. Il paziente non può esigere trattamenti sanitari contrari a norme di legge, alla deontologia professionale o alle buone pratiche clinico-assistenziali; a fronte di tali richieste, il medico non ha obblighi professionali*).

dignity must be guaranteed in a protective, neither paternalistic, nor destructive function.[137]

Tafida's case could represent a turning point. Indeed, in this case Justice MacDonald reserved a different significance to the interests of the parents, compared to that of all the other parties involved, considering sacred the values and religion professed by the child. However, it should be pointed out that these religious values are practised by her parents, who taught them to their five-year-old daughter. Reasonably, given her age, Tafida had not yet had time to form an autonomous religious idea or identity. Furthermore, the role of the parents apparently also prevailed over that of health professionals, both in their role as doctors and in their role as providers of public health services, as managing bodies of health structures.[138] In these circumstances, the potential risk arises of putting the professional obligations of healthcare professionals and such institutions towards children in the background, giving priority to those of the parents.[139] In this context, the moment in which the patient's clinical picture is so compromised that the therapeutic intervention is transformed from curative to clinically inappropriate and ethically disproportionate,[140] becomes decisive, without any improvement in the state of health or quality of life in favour of the patient. It is emphasised that the concept of "proportionality of care" emerges from Catholic doctrine and refers to the suspension of therapeutic means when their use does not obtain the expected result, taking into account the physical and moral conditions of the sick person.[141] On the basis of this, the renunciation of therapeutic persistence is morally justified, even by the Church.[142] Alta's case shows a further step: the

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[137] Conti, Roberto. 2018. La legge 22 dicembre 2017, n. 219 in una prospettiva civilistica: che cosa resta dell'art. 5 del codice civile? https://www.giurcost.org/studi/conti8.pdf. (Last accessed on 7 December 2021).

[138] Cave Emma, Brierley Joe, and David Archard, cit.

[139] Cave Emma, Brierley Joe, and David Archard, cit.

[140] According to Article No. 16 of the Codice di deontologia medica (2014) (Code of medical ethics).

[141] Sacred Congregation for the Doctrine of the Faith, Declaration on euthanasia, 5.5.1980, http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_19800505_euthanasia_en.html (Last accessed on 7 December 2021).

[142] According to Pope Francis' words: "*It is clear that not adopting, or else suspending, disproportionate measures, means avoiding overzealous treatment; from an ethical standpoint, it is completely different from euthanasia, which is always wrong, in that the intent of euthanasia is to end life and cause death*.

traditional religious "sanctity of life" principle (fundamental, but not immutable), according to which every single life must be defended, seems to surrender to the protection of the dignity of the young patient, avoiding her suffering, since, on the one hand, her burden of pain will increase without any prospect of improving her medical condition, and, on the other hand, her cognitive impairment will not change.[143]

In the specific case of paediatric clinical trials, children grow up and mature at different ages to adolescents or adults and this makes them a non-uniform subgroup.[144] For example, "*(T)he needs and biological and physiological characteristics of neonates are very different compared to teenagers. Therefore, additional age-appropriate research is often needed, making the process of developing paediatric medicines more complex.*"[145]

Scholars put forward some proposals that could help to solve such problems. On the one hand, there are those who point out that in cases of rare disease it is not possible to carry out an experiment according to the canonical protocols, therefore posing the question of whether or not it is possible, exceptionally, to develop further protocols or innovative experimental methodologies, to be applied without delay on patients who have already exhausted all conventional treatments.[146] Regarding consequences of side effects, previously unknown to the experimentation, a limitation of the experimental time, to make it shorter than the usual ones, could be suggested.[147] It is probable that such suggestions may cause some doubts in the scientific community, but it seems appropriate to open a discussion on possible

(http://www.vatican.va/content/francesco/en/messages/pont-messages/2017/documents/papa-francesco_20171107_messaggio-monspaglia.html). (Last accessed on 7 December 2021).

[143] [2021] EWHC 1426 (Fam), cit.

[144] Report from the Commission to the European Parliament and the Council, State of paediatric medicines in the EU - 10 years of the EU Paediatric Regulation COM(2017)626,Bruxelles, 2017, 2, on https://ec.europa.eu/transparency/documents-register/detail?ref=COM(2017)626&lang=en (Last accessed on 7 December 2021).

[145] Report from the Commission, cit. 2.

[146] Wilkinson, Dominic, and Savulescu, Julian, cit.

[147] Wilkinson, Dominic, and Savulescu, Julian, cit.

remedies that can be studied and shared by the ethical, scientific and legal communities.

The basic legal question that remains unanswered with respect to the ethical and legal questions relating to this issue, concerns how to manage the conflicts of interest that oppose parents to their children in order to prevent children, especially infants, from being exploited as guinea pigs. At this point it is necessary to strengthen the transparency and trust in the relationship with health professionals, even if this is difficult in times of increasing collective discredit of science, but it is necessary to protect children's best interest. However, the concept of trust takes on a different value here, as it constitutes a question of life and death, and the law should not overstep the bounds of ethics in resolving such issues.