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The Evolution of One Health Concept – A European Perspective

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Abstract: Over the past years, the European Union has been engaged in activities aimed at finding solutions to protect health in accordance with interdisciplinary and transdisciplinary thinking in line with the One Health approach. The experiences related to the COVID-19 pandemic, clearly demonstrated the close connection between humans, animals, and the shared environment and increased interest for this approach to be applied and translated into action. This paper seeks to present the readiness of the European Union and its institutions for the challenges related to the political and legal approach and implementation of One Health concept.

1. Introduction

Health, which is one of the fundamental values to be protected, is constantly exposed to risk factors. The aim of medical sciences and the policy measures taken by public authorities is to diagnose these risks and effectively prevent them. In this area, the operating model of public authorities relies on the achievements of these sciences. Searching for sources and methods of diagnosing threats to public health, the authorities have developed the One Health concept as a tool allowing for more effective and targeted identification of risk foci. From the very beginning, the concept required a multi-sectoral approach, involving doctors, veterinarians, and epidemiologists, as well as other stakeholders, including public authorities themselves.

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Today, it seems obvious that the One Health concept[1] is necessary for enabling interdisciplinary and transdisciplinary thinking and action from a public health perspective. It is based on the general assumption that human health, animal health, and environmental conditions are interconnected, and the influence of these areas on each other is not neutral. This interaction must therefore always be taken into account in all measures aimed at protecting the health of people, animals, plants, and ecosystems.[2] Therefore, it can be argued that the presented approach should have a universally accepted cross-sectional value.

The approach based on the One Health concept, which originated in medical sciences, over time attracted interest in the area of social sciences, initially mainly for theoretical merits. The experience of the last few years shows that this concept has also impacted the political introversion, including the law. It is taken into account in the planned strategies and legal regulations adopted by EU institutions.[3] Intensified activities in this area are determined, on the one hand, by the recent crises, including the related failures that the international community has suffered, in particular in connection with the COVID-19 pandemic, and, on the other hand, by the inevitable conclusion that continued application of the current approach, based on the paradigm of separation and autonomy of the spheres of human, animal, and environmental health, cannot allow for effective achievement of public health objectives.

The paper examines political and legal documents issued by EU bodies, and initiatives undertaken to identify the current stage of implementation of the concept into the political and legal systems of the EU. By tracing its penetration from the field of medical sciences, the paper asks an additional question regarding the EU's readiness to operationalize this concept, primarily from the point of view of institutional preparation. For the One

1 Sarah J. Pitt and Alan Gunn, "The One Health Concept," *British Journal of Biomedical Science* 81 (2024): 12366, https://doi.org/10.3389/bjbs.2024.12366.

2 Ronald M. Atlas, "One Health: Its Origins and Future," *Current Topics in Microbiology and Immunology* 365 (2013): 1–13, https://doi.org/10.1007/82_2012_223.

3 See as an example: Regulation (EU) 2021/522 of The European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021–2027, and repealing Regulation (EU) No 282/2014 (O.J.E.C. L107/1, 26 March 2021).

Health concept to be fully implemented, certain conditions must be met, as both political strategies and the framework set by the law must refer to the effects achieved as a result of research carried out, in particular in the field of medical science, and their applications. In light of the above, the author aim to examine the extent to which the EU authorities are ready to adopt and implement policies in line with the One Health approach, referring to international factors that provide the motivation and support for these measures.

The article employs methods of descriptive and sociological analysis. The focus was on describing the impact of concepts originating from life sciences as a factor determining the area of social functioning related to public health and its impact on the administrative policies and the legal provisions adopted by the EU. This method was complemented by a law-dogmatic analysis.

2. One Health Concept in the Medical Sciences

To better understand the assumptions underlying the concept, which permeates the EU's political and legal system, it is necessary to refer to the conceptual and terminological findings made in the field of broadly understood medical sciences. The framework of the One Health concept, or the new perspective on ways to identify the sources of threats to public health, is not easy to define or rigorous. There is currently no universal standard definition of One Health.[4] However, there is no doubt that it is based on the assumption that human health, animal health, and environmental health are interconnected.[5]

[4] Michael Bresalier, Angela Cassidy, and Abigail Woods, "One Health in History," in *One Health: The Theory and Practice of Integrated Health Approaches*, eds. Jakob Zinsstag et al. (CAB International, 2015), 1–14, accessed April 5, 2024, https://www.cabi.org/wp-content/uploads/Chap1-9781789242577.pdf; Maria Cristina Schneider et al., "'One Health'" From Concept to Application in the Global World," *Oxford Research Encyclopedia of Global Public Health*, April 26, 2019, accessed April 6, 2024, https://oxfordre.com/publichealth/view/10.1093/acrefore/9780190632366.001.0001/acrefore-9780190632366-e-29.

[5] Francesca Coli and Hanna Schebesta, "One Health in the EU: The Next Future?," *European Papers* 8, no. 1 (2023): 301–16.

Going back to its origins, it should be emphasized that the history of this concept is, in a sense, an extension of the One Medicine concept.[6] Sometimes these terms are used interchangeably, however, this is incorrect, as they are distinct from each other. One Medicine emphasized the cooperation between human and veterinary medicine,[7] and had a rather clinical connotation, which insufficiently reflected the interactions between human and animal health that reach far beyond individual clinical issues and include ecology, public health, and broader societal dimensions. It is observed that One Medicine is thus evolving into One Health through the practical implementation and careful validation of contemporary thinking on health and ecosystems and their relevance to the development of global public health and animal health.[8] The new approach embodied in the One Health concept also takes into account elements of the ecosystem and the environment as interdependent links that connect the other two.[9]

The integrated and systemic idea of health is of key importance here, as it not only determines the development of science but is also integrated into policies that are implemented in response to ongoing global changes. At the same time, bearing in mind the need to revise the current approach, it should be proposed that, for the effectiveness of the assumptions adopted in medical sciences, as well as the implementation of the developed

6 The origin of the One Medicine concept has been linked to the 19th century German physician and pathologist, Rudolf Virchow, whose discoveries on Trichinella spiralis in pork led to valuable public health measures. However, Calvin Schwabe made major advances in the field of public health through his writings and his position as Chair of a new Department of Epidemiology and Preventive Medicine at the University of California, Davis School of Veterinary Medicine. He is credited with having coined the term "One Medicine" and he strongly advocated for collaboration between professionals in human and veterinary public health to address zoonotic disease concerns. See: Carlton Gyles, "One Medicine, One Health, One World," *The Canadian Veterinary Journal* 57, no. 4 (2016): 345–6.

7 Tracey A. King, "The One Medicine Concept: Its Emergence from History as a Systematic Approach to Re-Integrate Human and Veterinary Medicine," *Emerging Topics in Life Sciences* 5,5 (2021): 643–54, https://doi.org/10.1042/etls20200353.

8 Jakob Zinsstag et al., "From 'One Medicine' to 'One Health' and Systemic Approaches to Health and Well-Being," *Preventive Veterinary Medicine* 101, no. 3–4 (2011): 148–56, http://dx.doi.org/10.1016/j.prevetmed.2010.07.003.

9 One Health has seen an unprecedented revival in the last decade with scientific debate, research programs (www.onehealthcommission.org), integrated disease surveillance (www.promedmail.org), and an open toolbox in the fields of disease surveillance, epidemiological studies and healthcare provision.

scientific outcomes in social policies and policies adopted in processes based on the One Health approach, it is necessary to ensure full communication, coordination, cooperation, and capacity building that will enable development.[10] Such conclusions follow from the multi-sectoral nature of this concept.

3. The One Health Concept as a Challenge for International Authorities

Findings made in the medical sciences have implications for the social and political spheres and pose a challenge to the international community. The challenge was to implement the arrangements introduced in the area of medicine in connection with the new approach to the social sphere. The first recommendations related to the One Health approach, addressed to governments and politicians, as well as scientific institutions, were contained in the "Manhattan Principles"[11] document issued in 2004. It was, in a way, the result of the impact of the global outbreak of Severe Acute Respiratory Syndrome coronavirus (SARS-CoV-1), which sharply highlighted the risks posed to humans by zoonoses.[12] The document emphasized the need for a broader understanding of the demands of health and disease and unity of approach achievable only through a consistent focus on human, domestic animal, and wildlife health, converging in the concept of One Health.

It was stressed that phenomena such as species loss, habitat degradation, pollution, invasive alien species, and global climate change are fundamentally altering life on the planet, from the wild areas on the land and ocean depths to the most densely populated cities. The rise of new and re-emerging infectious diseases threatens not only humans (and their food supplies and economies) but also the fauna and flora comprising the

10 Tomas C. Mettenleiter et al., "The One Health High-Level Expert Panel (OHHLEP)," *One Health Outlook* 18, no. 5 (2023), https://doi.org/10.1186/s42522-023-00085-2.

11 The principles were developed during a symposium organized in New York by the Wildlife Conservation Society "Building Interdisciplinary Bridges to Health in a Globalized World" in New York – "The Manhattan Principles," Wildlife Conservation Society, accessed April 6, 2024, https://oneworldonehealth.wcs.org/About-Us/Mission/The-Manhattan-Principles.aspx.

12 John S. Mackenzie and Martyn Jeggo, "The One Health Approach—Why Is It So Important?," *Tropical Medicine and Infectious Disease* 4, no. 2 (2019): 88, https://doi.org/10.3390%2Ftropicalmed4020088.

critically needed biodiversity that supports the living infrastructure of our world. In 2019, the "Manhattan Principles" were replaced by the "Berlin Principles,"[13] which focused on the need to update the previous document by reintegrating ecosystem health and integrity while also addressing current pressing issues, such as climate change and antimicrobial resistance that are intrinsically connected with human activity and profoundly influenced by it.[14] This update identified two main interdependent needs, which are still relevant today: to shed light on the environmental component of One Health, and to broaden the scope of One Health, which is largely limited to the epidemiological, medical, and veterinary fields.[15] The discussions on aspects of health and the factors that determine them, due to the multi-sectoral nature of the issue itself and the lack of terminological clarity, tended to concentrate on its conceptual and social dimensions.

Finally, the proposal for a comprehensive approach to One Health put forward in 2021, was made by the One Health High-Level Expert Panel (OHHLEP), a group of 26 independent experts on One Health, created thanks to the so-called Quadripartite (or Tripartite Plus), the partnership on One Health involving four international organizations: FAO, WHO, OIE, and UNEP.[16] According to the definition:

> One Health is an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals and ecosystems. It recognizes that the health of humans, domestic and wild animals, plants, and the wider environment (including ecosystems) are closely linked and inter-dependent.

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13 In 2019, the "One Planet, One Health, One Future" conference, "The 2019 Berlin Principles on One Health," Wildlife Conservation Society, accessed April 6, 2024, https://oneworldonehealth.wcs.org/About-Us/Mission/The-2019-Berlin-Principles-on-One-Health.aspx.

14 Kim Gruetzmacher et al., "The Berlin Principles on One Health – Bridging Global Health and Conservation," *Science of The Total Environment* 764 (2021): 142919, https://doi.org/10.1016/j.scitotenv.2020.142919.

15 Coli and Schebesta, "One Health in the EU," 306.

16 The One Health Quadripartite was launched on 17 March 2022; it consists of four global organizations: The World Health Organization (WHO), the World Organization for Animal Health (WOAH, formerly OIE), the UN Food and Agriculture Organization (FAO) and the UN Environment Programme (UNEP), see: "Quadripartite Memorandum of Understanding (MoU) Signed for a New Era of One Health Collaboration," UNEP, April 29, 2022, accessed April 6, 2024, https://www.unep.org/resources/publication/quadripartite-memorandum-understanding-mou-signed-new-era-one-health.

> The approach mobilizes multiple sectors, disciplines and communities at varying levels of society to work together to foster wellbeing and tackle threats to health and ecosystems, while addressing the collective need for clean water, energy and air, safe and nutritious food, taking action on climate change, and contributing to sustainable development.[17]

A new, important element in the proposed definition is a clear reference to the methodology and approach that allow for the practical implementation of the assumptions that lie at the core of this concept. OHHLEP provided input into the One Health Joint Plan of Action,[18] a strategic document outlining the way forward for the successful implementation of the One Health approach to tackle global problems at the human-animal-ecosystem interface. The purpose of adopting of the One Health Joint Plan of Action was also to support One Health implementation by member countries, enable collaboration across sectors and regions, identify synergies and overlaps to support coordination and mobilize investment including better use of resources. It should be noted here that the One Health Joint Plan of Action is also consistent with the key needs to achieve the United Nations Sustainable Development Goals[19] and provides guiding principles for policymakers, scientists and practitioners. The One Health Joint Plan of Action has six interdependent Action Tracks which are focused on enhancing One Health capacities to strengthen health systems, reducing the risk of emerging zoonotic epidemics and pandemics, controlling and eliminating endemic zoonotic, neglected tropical and vector-borne diseases, strengthening the assessment, management and communication of food safety risks, curbing the silent pandemic of antimicrobial resistance and integrating the environment into One Health.

It was an important piece of advice for public authorities, but it also remains valid here. According to Principle 8 of the "Berlin Principles," enhancing the capacity for cross-sectoral and trans-disciplinary health

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17 Mettenleiter et al., "The One Health."

18 World Health Organization, Food and Agriculture Organization of the United Nations, World Organisation for Animal Health & United Nations Environment Programme, *One Health Joint Plan of Action (2022–2026): Working Together for the Health of Humans, Animals, Plants and the Environment* (Rome: World Health Organization, 2022), https://doi.org/10.4060/cc2289en.

19 "The 17 Goals," United Nations, 2023, accessed April 6, 2024, https://sdgs.un.org/goals.

surveillance and clear, timely information-sharing to improve coordination of responses between governments and non-governmental organizations, health, academia, and other institutions, the private sector, and other stakeholders. In this context, guidelines for public authorities seem to be clear, although in each specific case, questions remain as to what exactly should be done to ensure that the strategies adopted allow for the effective implementation of the One Health concept.

In this context, the One Health Quadripartite is a helpful initiative to guide the activities of stakeholders participating in One Health strategies. While the importance of cooperation at the global level cannot be overestimated, the implementation of the One Health approach cannot take place without significant involvement of authorities at the level of national policies and strategies. Notwithstanding the above, it should be borne in mind that, despite progress towards a common approach, specific approaches adopted in these areas may differ.

In this context, it is worth recalling the impact of the work and arrangements established by One Health Quadripartite and adopted in December 2023 as "The guide to implementing the One Health Joint Plan of Action at national level."[20] The document highlights actionable pathways such as governance, sectoral integration, and knowledge, with the view to ensuring a successful implementation of One Health. It is designed to support countries at different stages of implementing One Health by encouraging teamwork and the engagement of different sectors. In this perspective, which is aligned with the 2030 Sustainable Development Goals, One Health is recognized as a key part of keeping people healthy in the long term. It brings different sectors such as health, agriculture, and education together to work towards common goals and make sure that everyone's health is covered. While the members of the Quadripartite have a mandate to focus on tackling challenges across human, animal, plant, and environmental domains, their efforts aim to foster a more integrated and coordinated approach.

[20] The guide to implementing the One Health Joint Plan of Action at the national level was launched during the United Nations Climate Change Conference (COP28) held from November 30 to December 13 at Expo City in Dubai, United Arab Emirates. See: "The Guide to Implementing the One Health Joint Plan of Action at National Level," UNEP, December 10, 2023, accessed April 6, 2024, https://www.unep.org/resources/report/guide-implementing-one-health-joint-plan-action-national-level.

Another positive value of the cited document is the indication of six areas where actions should be taken to implement the One Health approach. In particular, the six areas to focus on include laboratory services, control of zoonotic diseases, neglected tropical diseases, antimicrobial resistance, food safety, and environmental health,[21] and, above all, the paths and stages of implementation of One Health into national policies,[22] also affecting the actions taken by the EU authorities.

In the context of the assumptions of the One Health concept outlined above, action at the international level seems to be necessary, primarily due to the integrated and coordinated approach adopted in the One Health assumptions, which is not only helpful at the national level but also positively affects the way tasks are carried out by a supra-national organization such as the EU.

4. One Health Concept in EU Policies

In the area of EU policies assigned to the executive body of the European Union responsible for current policy, the One Health approach has undergone a certain evolution, similar to that which happened in the medical sciences. A detailed analysis in this respect has been provided in the article by F. Coli and H. Schebesta, who pointed to the clear evolution of this concept since 2010.[23] By dividing the timelines defining the measures taken by the European Commission in relation to the One Health concept into four parts, they indicated that there has been an evolution both with regard to the One Health concept itself and to the way it has been approached. The authors pointed out that in the first period, One Health was not perceived as an autonomous concept, separate from the "Manhattan Principles"; instead, it appeared at best as an "initiative" of the international arena. In fact, initially, the European Commission recognized One Health as an expression of the unique link between human and animal health, without taking environmental health into account. The breakthrough came with the adoption

21 Pitt and Gunn, "The One Health Concept."

22 See: "The Guide to Implementing the One Health Joint Plan of Action at National Level," 11.

23 See: Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions The EU Role in Global Health SEC(2010)380 SEC(2010)381 SEC(2010)382, COM/2010/0128 final.

of the European Green Deal[24] in 2019; from then on, the documents refer directly and explicitly to the One Health concept. The European Green Deal as an example of policy initiatives of the European Commission responds to problems related to the climate and the natural environment, considering this to be the most important task facing the current generation. First of all, the document refers to the fact that the atmosphere is warming and the climate is changing every year. It is a new growth strategy that aims to transform the EU into a fair and prosperous society with a modern, resource-efficient and competitive economy that achieves net zero greenhouse gas emissions by 2050 and decouples economic growth from the use of natural resources. It also aims to protect, conserve and enhance the EU's natural capital, and protect the health and well-being of citizens from environment-related risks and impacts.

During the transition period, in 2017, the EU One Health Action Plan Against Antimicrobial Resistance AMR[25] was launched, bringing a change of direction in the approach to the above-mentioned issue. Importantly, the cited document introduced a legal definition of the concept of One Health, according to which:

> One Health: is a term used to describe a principle which recognizes that human and animal health are interconnected, that diseases are transmitted from humans to animals and vice versa and must therefore be tackled in both. The One Health approach also encompasses the environment, another link between humans and animals and likewise a potential source of new resistant microorganisms.[26]

It may seem that the perspective on the issue is narrow because the European Commission did not consider the three dimensions of One Health as equally important. Yet, it should be emphasized that the Action Plan

[24] See: Communication From The Commission To The European Parliament, The European Council, The Council, The European Economic And Social Committee And The Committee Of The Regions The European Green Deal Brussels, 11 December 2019, COM(2019) 640 final. See: Communication From The Commission To The Council And The European Parliament A European One Health Action Plan against Antimicrobial Resistance (AMR), COM/2017/0339 final.

[25] Ibid.

[26] Ibid., 3.

document itself refers to the need to address a broad concept that includes environmental factors, identifying AMR as one of the problems to which the One Health concept should be applied in such a broad approach.

Following the open adoption of the assumptions of the One Health concept, there are several policy strategies under the European Green Deal, including the Biodiversity Strategy to 2030,[27] the Zero Pollution Action Plan,[28] the Farm to Fork strategy,[29] the Chemical Strategy for Sustainability,[30] and the Pharmaceutical Strategy for Europe.[31] The latter refers directly to the Plan Against AMR, which is the European One Health action plan to combat antimicrobial resistance. Moreover, the adopted policies also indicate other important areas of One Health including pandemic prevention, biodiversity loss, chemical pollution, and food system sustainability.

Therefore, there has been a clear change over time in the way the One Health concept has been approached, understood, and implemented. This is particularly clear in the document on Building a European Health Union,[32] which pointed out that it currently requires a systemic,

27 Communication From The Commission To The European Parliament, The Council, The European Economic And Social Committee And The Committee Of The Regions, EU Biodiversity Strategy for 2030 Bringing nature back into our lives, Brussels, 20 May 2020, COM(2020) 380 final.

28 Communication From The Commission To The European Parliament, The Council, The European Economic And Social Committee And The Committee Of The Regions Pathway to a Healthy Planet for All EU Action Plan: Towards Zero Pollution for Air, Water and Soil, Brussels, 12 May 2021, COM(2021) 400 final.

29 Communication From The Commission To The European Parliament, The Council, The European Economic And Social Committee And The Committee Of The Regions A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system, Brussels, 20 May 2020, COM(2020) 381 final.

30 Communication From The Commission To The European Parliament, The Council, The European Economic And Social Committee And The Committee Of The Regions Chemicals Strategy for Sustainability Towards a Toxic-Free Environment, Brussels, 14 October 2020, COM(2020) 667 final.

31 Communication From The Commission To The European Parliament, The Council, The European Economic And Social Committee And The Committee Of The Regions Pharmaceutical Strategy For Europe {Swd(2020) 286 Final}, Brussels, 25 November 2020, COM(2020) 761 final.

32 Communication From The Commission To The European Parliament, The Council, The European Economic And Social Committee And The Committee Of The Regions Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats, Brussels, 11 November 2020, COM(2020) 724 final.

forecast-based approach that takes into account the interactions between human and animal health and the environment to develop structural solutions adapted to future challenges, in line with the One Health approach.

This approach is continued in the EU Global Health Strategy.[33] One of its guiding principles refers to applying a comprehensive One Health approach and intensifying the fight against antimicrobial resistance. The Commission identifies two critical challenges that have become more urgent in recent years. The first can be defined as the complexity and the consequences of animal, environmental, and human interactions, which require a multisectoral, integrated, and transdisciplinary One Health approach. The second is the invisible pandemic of antimicrobial resistance. To develop this guiding principle, the Commission identifies lines of action that should be prioritized. These include intensifying cooperation with the Quadripartite to implement its One Health Joint Plan of Action, as well as seeking "deep prevention,"[34] which stands for identifying and addressing threats before pathogens cross from animals to humans, rather than after human outbreaks have occurred, and strengthening the capacity to prevent pollution-related health threats.

This was highlighted in the document on the Future of Europe,[35] stressing the need for a broader understanding of health. This approach would lead to the adoption of a holistic approach to health, addressing, beyond diseases and cures, health literacy and prevention, and fostering a shared understanding of the challenges faced by people who are ill or disabled, in

33 Communication From The Commission To The European Parliament, The Council, The European Economic And Social Committee And The Committee Of The Regions EU Global Health Strategy Better Health for All in a Changing World, Brussels, 30 November 2022, COM(2022) 675 final.

34 Jorge Vinuales et al., "A Global Pandemic Treaty Should Aim for Deep Prevention," *The Lancet* 397, no. 10287 (2021): 1791–2, accessed April 6, 2024, https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00948-X/fulltext.

35 See: Communication From The Commission To The European Parliament, The European Council, The Council, The European Economic And Social Committee And The Committee Of The Regions Conference On The Future Of Europe Putting Vision into Concrete Action, Brussels, 17 June 2022, COM(2022) 404 final.

line with the One Health approach, which should be describe as a horizontal and fundamental principle encompassing all EU policies.[36]

In light of this abbreviated and simplified overview of EU policies on the timeline of changing approaches to One Health, it should be noted that, during the period under review, One Health has gained greater legitimacy than in the past, when it was recognized as an "initiative" or a "concept." While it is still undergoing transformation, it is currently perceived as a "principle" and an "approach." This change has a direct impact on the meaning of One Health within the European system. The term "approach" suggests a methodology that should be applied by institutions in their procedures and that should be taken into account by policy-makers in the policy-cycle process, as well as by the judicial bodies in their legal interpretation. Meanwhile, the term "principle" paves the way for a new configuration of One Health and means that it should be taken into account by policy-makers in the policy-cycle process, and by the judicial bodies in their legal interpretation.[37] Over time, there has been an evolution in the way in which One Health is perceived as a policy tool, as well as in the scope of the area to which the European Commission addresses tasks.

5. One Health in EU Legislation

Legislation is the area where the principles that guide the EU's policies are implemented. This is a place where they acquire normative force, and where specific institutions and legal instruments are put in place to implement them. Assuming that One Health is treated in EU policies both as a principle and as an approach directed, in particular, at public authorities, it has also been reflected in the adopted legislation. However, as the concept itself has evolved, so did the normative approach, reflecting the state of the current public debate and the way issues are dealt with.[38]

In the area of legislation related to One Health, the earliest references to this concept can be found, in particular, in recitals of the Animal Health

36 See: COM(2022) 404 final, Annex, 8.
37 Coli and Schebesta, "One Health in the EU," 310.
38 Ibid., 311.

Law Amendment[39] or the Veterinary Medicinal Products[40] regulations, which referred to a narrow understanding, emphasizing the interdependence of human and animal health in the context of AMR.[41] Similar references can be found in Official Controls from Third Countries Regulation,[42] and the Horizon Europe Regulation.[43] It seems, however, that the concept of One Health understood in a broad sense currently begins to dominate in the adopted law. This perspective is reflected primarily in the presentation adopted in the EU4Health Programme Regulation.[44] Basically the EU-4Health Programme Regulation focuses on reinforcing the EU's resilience for cross-border health threats including actions directed at strengthening preparedness planning and response capacity at national and Union level, at reinforcing the role of the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA), and at establishing a health emergency preparedness and response authority. Such actions could include building capacity for responding to health crises, preventive measures related to vaccination and immunization, strengthened surveillance programs, provision of health information, and

39 Regulation (EU) 2016/429 Of The European Parliament And Of The Council Of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law', O.J.E.C. L84/1, 31 March 2016), 1–208.

40 Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (Text with EEA relevance, O.J.E.C. L4, 7 January 2019), 43–167.

41 See: Adriana Kalicka-Mikołajczyk, "Unia Europejska wobec kwestii zwalczania oporności na środki przeciwdrobnoustrojowe," in *Prawo międzynarodowe wobec wyzwań społecznych*, eds. Ewelina Cała-Wacinkiewicz et al. (Warsaw: C.H. Beck, 2023), 261–8.

42 Regulation (EU) 2021/1756 of the European Parliament and of the Council of 6 October 2021 amending Regulation (EU) 2017/625 as regards official controls on animals and products of animal origin exported from third countries to the Union in order to ensure compliance with the prohibition of certain uses of antimicrobials and Regulation (EC) No 853/2004 as regards the direct supply of meat from poultry and lagomorphs (O.J.E.C. L357/27, 8 October 2021).

43 Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014 (O.J.E.C. L427/17, 30 November 2021).

44 Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021–2027, and repealing Regulation (EU) No 282/2014 (Text with EEA relevance, O.J.E.C. L107, 26 March 2021).

platforms to share best practices. In this context, the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness and surveillance, and the management capacity and response capacity of actors at Union and Member State levels, including contingency planning and preparedness exercises, in keeping with the "One Health" and "Health in All Policies" approaches.[45]

It directly considers the One Health approach[46] as a multi-sectoral approach, which recognizes that human health is linked to animal health and the environment, and that actions to counteract health threats must take these three dimensions into account. Additionally, it identifies the objectives of the Regulations 2021/522 which have to improve human health across the Union and ensure a high level of protection of human health in all Union policies and activities, taking the One Health approach into account where applicable. An example of the implementation of such an approach in terms of an eligible action[47] is supporting actions aimed at increasing the supply, availability, and affordability of medicinal products, medical devices, and products relevant in the context of the crisis by supporting sustainable production and supply chains and innovation in the Union. The aforementioned actions should be implemented to facilitate the establishment and functioning of a cross-sectoral coordination mechanism in accordance with the One Health approach.[48]

In the context of the regulations adopted, the question arises as to whether the new approach, so openly manifested and used as a political instrument, affects the current way of achieving the goals set in the area of health. It was accurately pointed out that this way of perceiving the One Health approach may be recognized as a binding legal principle and constitute a new paradigm not only for the health sector in the strict sense but also for related sectors, i.e. food, pharmaceutical, chemical, or environmental.[49] At the same time, it should be noted that no mechanisms have been introduced to enable the decoding of the One Health principle in direct connection with Article 168(1) TFEU which lays down directives

45 See: Recital 11 Regulation (EU) No 282/2014.
46 Article 2(5) of the Regulation 2021/522.
47 Article 12 of the Regulation 2021/522.
48 See: Annex 1 to the Regulation 2021/522.
49 Coli and Schebesta, "One Health in the EU," 312.

concerning the maintenance of a high standard of protection of human health in all Union policies and activities, as well as with Article 11 TFEU which refers to environmental protection requirements or Article 13 TFEU which refers to animal welfare. There is no doubt that One Health has become a useful tool in policy planning and implementation, which clearly defines the chosen direction; one should not forget about the strong recommendation expressed in Communication 2022 that One Health should be conceptualized as a "horizontal and fundamental principle encompassing all EU policies,"[50] although fitting legislation and effective implementation, monitoring, and enforcement of the One Health approach continue to be a challenge for the EU.

6. Institutionalization of the One Health Approach in the EU

Given that the concept of One Health is understood as a new approach or principle in implementing public policies related to health in the broad sense, there is a need to provide it with institutional support. Looking from a relatively short-term perspective, which adopts the agreed One Health approach, no new institutional solutions dedicated exclusively to the implementation of the One Health approach in the EU have been created so far. At most, we can see their beginnings stemming from cooperation and joint activities launched between EU institutions. This is undoubtedly influenced by the fact that the concept itself and the way it is understood are changing and, above all, regardless of the currently adopted idea, there is still a huge challenge in operationalizing One Health,[51] due to its intersectoral and interdisciplinary nature. At the same time, there is no doubt that transdisciplinary cooperation in providing scientific advice to policy-makers in this regard is necessary, as this approach seems to be the most effective and sustainable in ensuring the prevention, preparedness, and early detection of risks and threats to health and wellbeing.[52]

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50 See: COM(2022) 404 final Annex, 8.

51 Patricia A. Conrad, Laura A. Meek, and Joe Dumit, "Operationalizing a One Health Approach to Global Health Challenges," *Comparative Immunology, Microbiology and Infectious Diseases* 36, no. 3 (2013): 211–6.

52 Jakob Zinsstag et al., "Advancing One Human–Animal–Environment Health for Global Health Security: What Does the Evidence Say?," *The Lancet* 401, no. 10367 (2023): 591–604.

In the network of European institutions, EU agencies are usually perceived as knowledge centers, bringing together know-how to support decision-makers in formulating, adopting, implementing, and assessing policies. However, while they have traditionally dealt with aspects of human, terrestrial and aquatic animal, plant, and ecosystem health in silos, now they need to take a broader perspective and move towards One Health approach.[53] They need to be redesigned,[54] increase their ability to understand cooperation, and ensure greater flexibility.[55] It should be noted that the experience resulting from cooperation during the COVID-19 pandemic[56] has undoubtedly been helpful and has contributed to the development of certain standards. Since that time, the range of competences of EU Agencies, and methods of cooperation in acquiring and exchanging data needed to implement the One Health approach have been strengthened, but there is still a need for remodeling.

Soft change has been carried out through joint initiatives, including programs involving other stakeholders, an example of which is *The One Health European Joint Programme* (OHEJP), established in 2018 to address challenges of interdisciplinary coordination. It boasts a landmark partnership between 37 partners across 19 member states in Europe and the Med-Vet-Net-Association.[57] The OHEJP is in active dialogue with the key European agencies, the European Centre for Disease Prevention and Control (ECDC), and the European Food Safety Authority (EFSA), to ensure that One Health needs are addressed synergistically. This approach aims to improve cross-disciplinary collaboration and communication, which in

53 Stef Bronzwaer et al., "One Health Collaboration with and among EU Agencies – Bridging Research and Policy," *One Health* 15 (2022), accessed March 13, 2024, https://www.sciencedirect.com/science/article/pii/S2352771422000969.

54 Ibid., 3.

55 In October 2020, the European Court of Auditors released a Special Report 22/2020: "Future of EU agencies – Potential for more flexibility and cooperation," accessed March 14, 2024, https://op.europa.eu/webpub/eca/special-reports/agencies-performance-audit-22-2020/en/.

56 Claudia Seitz, "The European Health Union and the Protection of Public Health in the European Union: Is the European Union Prepared for Future Cross-Border Health Threats?," *ERA Forum* 23 (2023): 543–66.

57 Helen L. Brown et al., "The One Health European Joint Programme (OHEJP) 2018–2022: An Exemplary One Health Initiative," *Journal of Medical Microbiology* 59, no. 8 (2020): 1037–9, accessed April 13, 2024, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7642980/.

turn facilitates the OHEJP's efforts to translate science into policy and enables it to tackle foodborne zoonoses, antimicrobial resistance, and emerging infectious threats on a much larger scale.

Further examples of interinstitutional initiatives include the cooperation between the European Environment Agency (EEA) and the European Chemicals Agency (ECHA); as well as the European Environment Agency (EEA), the European Food Safety Authority (EFSA), and the European Medicines Agency (EMA). They were undertaken to ensure that scientific advice by EU agencies can be increasingly integrated and aligned with the One Health approach. Since 2023, this collaboration has been further strengthened by the establishment of a cross-agency task force on One Health. In order to support the implementation of a One Health approach within and among the agencies, the task force focuses on five strategic objectives. They refer to facilitating strategic coordination of the work of agencies, promoting research coordination, providing a forum for the coordination of activities to update, inform and support the EU, policy-makers and other relevant stakeholders in their goal to prioritize One Health. Providing scientific advice in key areas such as food safety, global public health, biodiversity, and chemical pollution is also an important element as well as strengthening joint activities and the sharing of information on One Health aspects among the agencies, including by identifying interlinkages, interdependencies and fields of cooperation and providing a platform for the exchange of good practices within individual agencies.[58] The five EU agencies published the joint statement titled "Cross-agency knowledge for One Health action" on the occasion of the "One Health for All, All for One Health" conference organized by the European Commission.[59] The statement outlines the agencies' shared commitment to the One Health agenda in Europe and highlights a number of priorities for One Health action.

[58] See: "One Health Cross-Agency Task Force. Strengthening EU Agencies' Scientific Advice on One Health," EFSA, accessed March 13, 2024, https://www.efsa.europa.eu/sites/default/files/documents/news/one-health-cross-agency-task-force.pdf.

[59] See: "Cross-Agency Knowledge for One Health Action," European Environment Agency, published 13 November 2023, modified 23 May 2024, accessed April 6, 2024, https://www.eea.europa.eu/en/topics/at-a-glance/health/cross-agency-knowledge-for-one-health-action-statement.

Following these actions, in May 2024, the five agencies presented a framework for action that aims to guide the work of the cross-agency One Health task force for the period 2024–2026.[60] Its main objective is to strengthen cooperation to support the implementation of the One Health agenda in the European Union (EU).

The presented sequence of actions corresponds to a certain extent to the postulates reported in the literature, as there is an urgent need to define research requirements from a One Health perspective. However, the recommendations go much further, and call for the establishment of a transdisciplinary One Health Research and Innovation governance, both at national and EU levels.[61]

The measures taken so far are not based on a strongly institutionalized mechanism and therefore do not provide long-term funding. The lack of institutional support that would adequately coordinate the collection and use of information from various areas of medicine, veterinary medicine, and environmental sciences hinders the effective implementation of the One Health approach.

7. Summary

It seems obvious that the One Health concept is necessary for enabling interdisciplinary and transdisciplinary thinking and action from a public health perspective.

The concept itself, in its theoretical assumptions, does not seem to raise any major doubts. However, its conceptualization and implementation raise many practical problems. They undoubtedly require a change in the current systemic approach, starting with the preparation of representatives of medical, veterinary, and environmental sciences to act in line with the One Health approach, through the creation of institutional solutions, including financial ones, to enable research to be carried out according to the proposed approach. It is fundamentally different from the previous one.

60 See: "Cross-Agency One Health Task Force Framework for Action, 2024–2026," European Centre for Disease Prevention and Control, 7 May 2024, accessed May 16, 2024, https://www.ecdc.europa.eu/sites/default/files/documents/cross-agency-one-health.pdf.

61 Stef Bronzwaer et al., "One Health Collaboration," 4.

There is also the issue of transdisciplinary cooperation in providing scientific advice to policy-makers.

The presented policy initiatives and legal solutions adopted by EU bodies in relation to One Health show a slow but visible change in approach. It concerns both the scope of this concept and the way it is used in the social, political, and legal contexts. Both in the narrow sense, limited to actions taken in relation to combating antibiotic resistance, as well as in a broad sense, related to the efforts made towards achieving health, while taking all relevant factors into account, One Health recognizes the interconnection between human health, the environment, and animal health. Thus, the new paradigm resulting from the One Health approach becomes a factor that directly affects not only the health sector in the strict sense, but also related sectors (food, pharmaceutical, chemical, or environmental). In this way, it has evolved from a concept into a principle and an approach that binds public authorities. Although this course of action appears to be necessary, it is not free of moral and legal dilemmas.[62]

However, the noticeable change in conceptual approach is not the only challenge in this area. Many doubts remain about the operationalization of One Health. Additionally, it should be noted that the rationality of the efforts made at the EU level, in terms of policies, legislation, and institutions, depends largely on the initiative and level of involvement of the Member States. Here, high significance should be attached to the intensification of work with the Quadripartite on implementing its One Health Joint Plan of Action, which should serve public authorities as a standard determining the direction in the quest for individual institutional solutions enabling the adoption of the One Health approach at the national level. The direction set for public authorities in connection with the adoption of the One Health concept seems to be a foregone conclusion to the policies adopted at the EU level. The question of whether its full implementation is possible, both at the level of the EU and in individual member states, should be left open at this point.

[62] Chris Degeling et al., "Implementing a One Health Approach to Emerging Infectious Disease: Reflections on the Socio-Political, Ethical and Legal Dimensions," *BMC Public Health* 15, no. 1307 (2015), https://doi.org/10.1186/s12889-015-2617-1.

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Social Enterprises and Health Care Services within the European Legal Framework

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Abstract: Social enterprises (SEs) are organizations that pursue a purpose of general interest through the carrying out of economic activities on a steady and permanent basis. Despite the legal, economic and social differences among the Member States (MSs) of the European Union, SEs display at least two similar characteristics. Firstly, SEs are capable of combining entrepreneurial activities together with the pursuit of a social mission. Secondly, SEs largely deliver health care services both independently and in close partnership with public authorities, either through public procurement or by means of direct co-operation agreements. In this perspective, modern welfare systems rely heavily on a significant proportion of health care services and benefits provided by SEs. In addition, in some MSs, such as Italy, SEs are supported by enabling legal frameworks, which also include some important tax benefits. Against this background, the article aims to shed light on the legal aspects and the role of SEs in the delivery of health care services as well as their contribution to ensuring citizens/patients their fundamental right to health.

1. Introduction

SEs are broadly defined as nonprofit distributing organizations that achieve (some of) their income through trading, both in public and private-sector

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markets, in order to accomplish a purpose of general interest.[1] SEs are then part of the third sector engaged in trade, through which they pursue their social aims.[2]

As part of the broad range of goals that SEs can pursue, they may also be engaged in the delivery of health and social care services, either as an alternative or complement to mainstream public services.[3] Moreover, in carrying out their activities, SEs may favor the employment of disadvantaged or hard-to-place groups of people.[4]

Over time, the combination of these two characters has contributed to a widespread acknowledgement of the role of SEs. They are regarded as innovative organizational forms that are capable of meeting the demand for health and social care services, while also creating new employment opportunities and workplace structures that are inclusive and enable worker productivity and well-being.[5]

In some MSs, SEs have gained their own specific legal recognition, whereas in others they are the result of a process of organizational adaptation of existing legal forms, such as associations, foundations, and social co-operatives.

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1 See: Francesca Calò et al., "Collaborator or Competitor: Assessing the Evidence Supporting the Role of Social Enterprises in Health and Social Care," *Public Management Review* 20, no. 12 (2018): 1790–814; and Antonio Fici, "Funzione e modelli di disciplina dell'impresa sociale in prospettiva comparata," in *Diritto dell'economia sociale*, ed. Antonio Fici (Naples: Editoriale Scientifica, 2016).

2 Michael J. Roy, Rachel Baker, and Susan Kerr, "Conceptualising the Public Health Role of Actors Operating outside of Formal Health Systems: The Case of Social Enterprise," *Social Science & Medicine* 172 (2017): 144–52.

3 Richard Hazenberg and Kelly Hall, "Public Service Spin-Outs in the UK: Towards a Theoretical Understanding of the Spin-Out Process," Paper presented at the 4th EMES European Research Network International Research Conference on Social Enterprise, University of Liege, Belgium, 01–04 July 2013.

4 The reference here is to "Work Integration Social Enterprises" (WISEs), a form of social enterprises designed to provide a supportive environment for vulnerable people. For a comprehensive analysis of these type of social enterprises, see: Isabel Vidal, "Social Enterprise and Social Inclusion: Social Enterprises in the Sphere of Work Integration," *International Journal of Public Administration* 28, no. 9–10 (2018): 807–25.

5 Terry Krupa and Shu-Ping Chen, "Psychiatric/Psychosocial Rehabilitation (Psr) in Relation to Vocational and Educational Environments: Work and Learning," *Current Psychiatry Reviews* 9, no. 3 (2013): 195–206.

It is noteworthy that both social and legal recognition of SEs has not been easy to achieve for at least two main reasons. Firstly, according to the European legal tradition, any kind of enterprise has long been assigned a profit motive only. It would therefore be hard to accept that an entrepreneurial organization could not achieve a profit as its main goal. There was also a widespread conviction among economists that the maximization of profits is a fundamental condition for the efficiency and success of any firm. Secondly, public authorities were for a long time the only entities responsible for the preparation and delivery of health and social care services Consequently, private entrepreneurs pursuing social goals were significantly reduced to a marginalized role.

However, the progressive recognition of the broader concept of enterprise, which may also include the pursuit of social aims, on the one hand, and the crisis of welfare state, on the other, has allowed for a thriving development of SEs across Europe. Currently, SEs play an essential role in the provision of health and social care services, especially due to their specific mission as well as their organizational and legal patterns. In this respect, not only are SEs often partners of public authorities in providing health care services,[6] they also actively and significantly contribute to ensuring European citizens' right to health by delivering the services that allow them to enforce the principles that welfare systems encompass in their legal frameworks.

Against this background, the article will analyze the legal and institutional aspects as well as the role of SEs in Europe in the provision of health care services, especially with reference to their capability of ensuring citizens' right to health. The article will also endeavor to prove that both EU law and national legal systems may offer legal frameworks conducive to the development of SEs.

The article is divided into seven sections. Section 1 outlines the reasons for analyzing SEs. Section 2 delves into the historical evolution of nonprofit organizations in Europe. Section 3 explains the relations between the

[6] Despite the differences between the national health and legal systems within the European Union, it is widely noted that SEs have developed less as competitors and more as collaborators of public authorities in the provision of health and care services in Europe. For a complete discussion on this issue, see: Calò et al., "Collaborator or Competitor," 1790–814.

crisis of welfare systems and the development of SEs. Section 4 is devoted to explaining the specific relationship between SEs and the provision of services of general interest. Sections 5 underlines the role of SEs in ensuring the right to health. Section 6 illustrates the innovative features of the recent Italian SEs Reform Act. Finally, section 7 includes some concluding remarks.

2. A Brief Historical Overview of the Role of Nonprofit Organizations in Europe

As SEs are, in a sense, the organizational and legal evolution of traditional nonprofit organizations, a brief historical analysis of these organizations is needed to fully grasp the modern features of SEs.[7]

In Europe, by the end of the eighteenth century, nonprofit organizations had long been engaged in charitable activities, such as social work, health and social care, alms housing and education, especially for the benefit of the needy.[8] Nonprofit and charitable organizations could be freely set up to pursue their public goals and perform their activities in these sectors. The role of public authorities at that time was to supervise and ensure that charities would carry out their activities according to their charitable status and purposes.[9]

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7 See: Antonio Fici, *The Law of Third Organisations in Europe. Foundations, Trends and Prospects* (Rome: Springer – Giappichelli, 2023).

8 Alun Withey, "Medicine and Charity in Eighteenth-century Northumberland: The Early Years of the Bamburgh Castle Dispensary and Surgery, c. 1772–1802," *Social History of Medicine* 29, no. 3 (2016): 467–89. In Italy, at the end of the thirteen century, there were 10 hospitals in Milan, among which the St. Stephan Hospital could provide 500 beds and welcome 350 babies and 1,000 adults. In 1624 Rome, there were 8 hospitals, 21 confraternities, 11 colleges and 17 national hospitals, providing services to people coming from Venice, Milan, Germany and other states. See: Alberto Cova, "La situazione italiana: una storia di non profit," in *Il Non Profit Dimezzato*, ed. Giorgio Vittadini (Milan: Rizzoli, 1997), 31–2. In Milan, the case of the "Cà Granda" Hospital is paradigmatic: it was a huge "enterprise" that provided food to 1,600 men (barbers, chemists, bookkeepers, tailors) every day, in addition to the inmates. In the eighteenth century, the hospital was the largest landowner of the State. See: Ettore Verga, *Storia della vita milanese* (Milan: Casa Editrice Nicola Moneta, 1931), 174.

9 In England, the relations between charities and the Government mostly revolved around co-operation and mutual support rather than on conflicts or antagonism. It was in the Government's interest to sustain and help charitable organizations to grow and develop, not only because such intervention would relieve the Government itself of a certain number of responsibilities but also because this approach was perfectly in line with the liberal culture of

The legal and social environment in which charitable organizations had developed until then changed dramatically in the nineteenth and twentieth centuries under the pressure of a new kind of approach towards charities and the establishment of the modern welfare state. Starting from the end of the eighteenth century, when the French Revolution broke out, suspicion and aversion towards charities began to grown in Europe, with the exception of England, especially because they were mostly considered to be connected to the Catholic Church.[10] On the one hand, the ideology of the Enlightenment postulated that the State was to be recognized as the only "voice" of the people's will. No other established body could then exist, as citizens had to strengthen the authority of the State in order to expand and protect their individual rights.[11] On the other hand, the mainstream

the time. Charities then performed their activities in several areas, such as education, elderly care, poor relief, etc., especially in the big towns during the Industrial Revolution. The urban population, which consisted of workers living in cities like London, Norwich and Bristol, was considered to be "a sort of wild, savage, not welcomed people, whom nobody knew and nobody visited." See: Gareth Jones, *History of Charity Law 1530–1827* (Cambridge: Cambridge University Press, 1967), 178. The history of British charities and voluntary sector has always been defined by the search for a partnership with the State. "In the late nineteenth century, the voluntary sector took the lead in establishing the nature of the partnership; in the later twentieth century it is Government that has proposed a new 'Compact' on relations between the two sectors (Home Office, 1998)." See: Jane Lewis, "Reviewing the Relationship between the 'Voluntary Sector' and the State in Britain in the 1990s," *Voluntas: International Journal of Voluntary and Nonprofit Organizations* 10, no. 3 (1999): 255–70.

10 Alceste Santuari, *Le ONLUS* (Padova: Cedam, 2012), 21. In 1850, in Piedmont (Italy), the Government passed some statutory acts that confiscated all the assets of religious organizations and prevented religious and charitable organizations from carrying out activities without a specific royal authorization. In 1890, other statutory acts incorporated private charitable organizations into public bodies, which were to be directly supervised by local governments and managed by public officers. Later on, Fascism hampered and absorbed nonprofit organizations into the corporatist State, thus making them operate like public agencies. In this perspective, the Fascist regime strengthened the Italian social security system by allowing only State authorities to be in charge of providing social and health care services.

11 "The 1789 French revolution radically changed the philanthropic landscape, instituting the State as the sole ruler and custodian of the 'public interest' of the French people. The Le Chapelier Act of 1791 dissolved all existing charitable associations and nationalized all foundations under the principle that "no one is allowed to incite citizens to have an intermediary interest [between their own and the State's], to separate them from the Nation by spirit of cooperation". The 1793 republican constitution formally assigned the responsibility of the welfare of French citizens to the State: "Society owes subsistence to the unfortunate citizens, either

economic doctrine of *laissez-faire* ventured that economic relations were to be governed by market-driven forces only, thus disregarding all organizations that were not established for the purpose of making a profit.

This cultural and economic approach became also a legal attitude. The French Civil Code of 1804 included a comprehensive regulation of corporations, but it did not recognize any role for charitable organizations, because they did not pursue an economic goal. Accordingly, foundations and associations, which were the main nonprofit legal forms, would henceforth be devoid of any entrepreneurial features, as they would not be considered capable of carrying out economic activities.

From the late 1940s, the concept of welfare state began to develop across Europe.[12] Public authorities were progressively entrusted with a wide range of public interest functions. Such tasks also implied that they would be in charge of delivering welfare services. Hence, nonprofit organizations started to lose their role as health and social care providers and began to carry out mainly advocacy activities,[13] thus eventually playing an even more minor role than in the past.

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by getting them work or by insuring means of subsistence to those who cannot work." See: Arthur Gautier, Anne-Claire Pache, and Valérie Mossel, "Giving in France: A Philanthropic Renewal after Decades of Distrust," *Research Center ESSEC Working Paper* 3 (2013): 1318.

12 The original idea of the modern welfare state dates back to the mid-40s of the last century in the UK, when the National Health Service was established. Lord William Henry Beveridge was one of the promoters and architects of the NHS. On 20 November 1942, William Beveridge submitted to the British Parliament a report titled "Social Insurance and Allied Services". It was the first and comprehensive analysis of welfare policies, which were to be regarded as an integrated and consistent combination compatible with a market economy. The Beveridge Report proposed the introduction of a universal social security coverage and a covenant between the Government and voluntary organizations: "The third principle is that social security must be achieved by co-operation between the State and the individual. The State should offer security for service and contribution. The State in organising security should not stifle incentive, opportunity, responsibility in establishing a national minimum, it should leave room and encouragement for voluntary action by each individual to provide more than that minimum for himself and his family". See: William Beveridge, "Social Insurance and Allied Services," *Bulletin of the World Health Organisation* 78, no. 6 (2000): 848.

13 The rationale for nonprofit advocacy role is that it promotes the "public interest", defined as the collective or indivisible interests of the general public. See: Craig J. Jenkins, "Nonprofit Organizations and Political Advocacy," in *The Nonprofit Sector. A Research Handbook*, eds. Walter W. Powell and Richard Steinberg, 2nd ed. (Yale University Press, 2006), 307.

3. The Crisis of the European Welfare Systems and the Rise of Social Enterprises

At any rate, this "minority condition" of nonprofit organizations was soon to change. During the 1970s, the European welfare systems began to crumble under the weight of financial and organizational difficulties. Declining economic growth and rising unemployment were at the root of this crisis, which led to growing public deficits, among other things. While public revenues grew at a slower rate than in the past, public expenditures increased faster, especially in countries with generous subsidies for the unemployed and for the retirees and pre-retirees. In the first stage, most European countries responded to the fiscal crisis by both reforming employment subsidies and restructuring, slowing down or blocking the growth in the public supply of health and social care services. The subsequent increasing inability of traditional welfare policies to respond to an ever-swelling demand for health and social care services has led to a legitimacy crisis of the European welfare regimes.[14]

When European policy makers realized that the decline in economic growth would be a lasting phenomenon, they tried to implement a wide-ranging reform of welfare systems. Measures were taken to reduce the impact of public services provision on the public budget and to adapt, at least in theory, the supply of services to users' needs.[15] These objectives were pursued by (a) decentralizing to local authorities certain powers to decide and implement social and health care polices,[16] (b) introducing

14 Bruno Palier, "A Long Good Bye to Bismarck? The Politics of Welfare Reforms in Continental Europe" (Paper presented at the RC19 conference on Social policy in a globalizing world: developing a north-south dialogue, 6–8 September 2007–07–18 Florence University), 9.

15 See: Hans Dubois and Robert Anderson, *Impacts of the Crisis on Access to Healthcare Services in the EU* (Dublin: European Foundation for the Improvement of Living and Working Conditions, 2013).

16 See: Dolores Jiménez and Peter Smith, "Decentralisation of Health Care and Its Impact on Health Outcomes," *Discussion Papers Centre for Health Economics* 5/10 (2005); Rosella Levaggi and Peter Smith, "Decentralization in Health Care: Lessons from Public Economics" (Paper prepared for Conference on Economics and Health Policy Centre for Health Economics, University of York, 16th December 2003).

prices and tariffs,[17] and (c) privatizing some public services.[18] These policies were expected to make the European welfare systems more efficient and dynamic. On the contrary, the same policies often negatively affected the most vulnerable groups of citizens, thus reducing social cohesion.[19]

However, such a negative effect was to be partly balanced by the emergence of the role of nonprofit organizations as service providers. They progressively developed due to the decentralization and privatization process of health care services, which resulted[20] in the separation of financing responsibilities from service provision. While in many European countries, the financing of health care services is still largely within the competence of public authorities, the provision of those services has been contracted out to nonprofit organizations.[21] From this perspective, the distinction between purchasers and providers[22] has allowed for a better acceptance of civil so-

17 See: Jan B. Oostenbrink and Frans F.H. Rutten, *Cost Assessment and Price Setting in the Dutch Healthcare System A contribution to Work Package 6 of the EU Funded Research Project 'HealthBASKET': Approaches for Cost/Price Assessment in Practice* (Rotterdam: Institute for Medical Technology Assessment (iMTA), 2005).

18 See: Hans Maarse, "The Privatization of Health Care in Europe: An Eight-Country Analysis," *Journal of Health Politics*, *Policy and Law* 31, no. 5 (2006): 981–1014; Martin Powell and Robin Miller, "Privatizing the English National Health Service: An Irregular Verb?," *Journal of Health Politics, Policy and Law* 38, no. 5 (2013): 1051–9.

19 See: Richard Clayton and Jonas Pontusson, "Welfare-State Retrenchment Revisited: Entitlement Cuts, Public Sector Restructuring, and Inegalitarian Trends in Advanced Capitalist Societies," *World Politics* 51, no. 1 (1998): 67–98.

20 See: Christopher Newdick, "Global Capitalism and the Crisis of the Public Interest – Sleepwalking into Disaster," in *Research Handbook on Disasters and International Law*, eds. Susan C. Breau and Katja Samuel (Cheltenham: Edward Elgar, 2016). See also: James Barlow and Martina Köberle-Gaiser, "The Private Finance Initiative, Project Form and Design Innovation: The UK's Hospitals Programme," *Research Policy* 37, no. 8 (2008): 1392–402.

21 Julian Le Grand, "Quasi-Markets and Social Policy," *The Economic Journal* 101, no. 408 (1991): 1256–67.

22 Steven Harrison and Gerald Wistow, "The Purchaser/Provider Split in English Health Care: Towards Explicit Rationing?," *Policy and Politics* 20, no. 2 (1992): 123–30; Liina-Kaisa Thynkkynen, Ilmo Keskimäki, and Juhani Lehto, "Purchaser–Provider Splits in Health Care—the Case of Finland," *Health Policy* 111, no. 3 (2013): 221–5; Elenka Brenna, "The Lombardy Health Care System," *Università Cattolica del Sacro Cuore – Milan, Quaderni dell'Istituto di economia dell'impresa e del lavoro* n. 63 – maggio (2011); Josep Figueiras, Ray Robinson, and Elke Jakubowski, eds., *Purchasing to Improve Health Systems Performance* (European Observatory on Health Systems and Policies Series, Open University Press, 2005).

ciety's initiatives and has made their public funding more viable.[23] It has also stimulated supply and has especially spurred new projects in a sector that for-profit enterprises regarded as of little interest to them.[24] This set of changes has supported a growth in the demand for private providers of health care services. It has also widened the range of social and health needs, which have consequently opened up new opportunities for the nonprofit sector.[25] Yet, probably the most distinctive feature of such an evolution of nonprofit organizations is related to the recognition of health care as one of the fundamental rights of the individual.[26] The increased blurring of the private sphere, where human rights were traditionally not applicable, and of the public powers accounts for a new way by which nonprofit organizations have been perceived by the public at large. These organizations are regarded as falling within the purview of human rights law. As such, not only are they called upon and engaged in the delivery of essential services, but they are also expected to ensure human rights entitlements.

The ever-increasing involvement of nonprofit organizations in the delivery of health care services has brought about some significant changes in their legal and organizational patterns.[27] From the 1980s and the 1990s, nonprofit organizations began to diversify the measures through which they obtained funds for their activities. In addition to the more traditional income deriving from donations and fundraising campaigns, nonprofit organizations also started to pursue economic activities to find new financial resources for their mission. Nonprofit organizations realized that income generation would improve the efficiency, effectiveness, quality and

23 Union, Committee of the Regions, "The Management of Health Systems in the EU Member States – The Role of Local and Regional Authorities," 21 July 2011.

24 See: Henry B. Hansmann, "The Role of Nonprofit Enterprise," *Yale Law Journal* 89, no. 5 (1980): 843.

25 See: Ruud Ter Meulen, Wil Arts, and Ruud Muffels, eds., *Solidarity in Health and Social Care in Europe* (Springer, 2001).

26 Birgit Toebes, "International Health Law: An Emerging Field of Public International Law," *Indian Journal of International Law* 55, no. 3 (2015): 299–328.

27 Over the last decades, various legal forms have been created to better institutionalize or embed such an evolution of a nonprofit organization, which has been generally identified with the definition of social enterprise.

diversity of services that they provided for the benefit of the public,[28] especially the more marginalized and vulnerable people.[29] Simultaneously, they improved their partnership with public authorities[30]: some systematic funding policies have helped to strengthen the role of nonprofit organizations. These have begun to provide services to respond to health and social needs and not simply to advocate specific group interests.[31]

Ever since then, nonprofit organizations have (re)gained an important role in the provision of welfare services, including health care, particularly for the benefit of local communities.[32] According to privatization and contracting-out processes, these services are often provided as the result of public tenders in which nonprofit organizations take part as private providers. As a consequence of these policies, in many European health systems, a large number of associations and foundations that traditionally did not operate on the market have progressively moved towards a new organizational form, namely the social enterprise.[33] This represents a legal qualification which is currently recognized in most European jurisdictions.[34]

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28 See: European Center for Non-Profit Law, "Legal Regulation of Economic Activities of Civil Society Organizations," Policy paper, Budapest, February 2015.

29 See: Conference of INGos of the Council of Europe, "The Contribution of NGOs to the Fight against Poverty and Social Exclusion in Europe" (document prepared by Jean-Pierre Golle Vice-President of the Grouping 'Extreme Poverty and Social Cohesion' Grouping of the Conference of INGOs of the Council of Europe International Movement ATD Quart Monde, September 2007).

30 Jennifer M. Coston, "A Model and Typology of Government-NGO Relationships," *Nonprofit and Voluntary Sector Quarterly* 27, no. 3 (1998): 358–82. Before such a turning point, the voluntary welfare sector, "when matched against the welfare state, was consistently viewed as the 'junior partner in the welfare firm' in terms of both overall size and scale of service delivery." Michael Chesterman, "Foundations of Charity Law in the New Welfare State," in *Foundations of Charity*, eds. Charles Mitchell and Susan R. Moody (Oxford: Hart Publishing, 2000), Chapter 9, 251. See also: Tony Bovaird, "Efficiency in Third Sector Partnerships for Delivering Local Government Services: The Role of Economies of Scale, Scope and Learning," *Public Management Review* 16, no. 8 (2014): 1067–90.

31 See: Walter Devillé et al., "Health Care for Immigrants in Europe: Is There Still Consensus among Country Experts about Principles of Good Practice? A Delphi Study," *BMC Public Health* 11 (2011): 699.

32 Chesterman, "Foundations of Charity Law," 250.

33 See: Calò et al., "Collaborator or Competitor," 1790–814.

34 See: Fici, "Funzioni e modelli di disciplina," 289; Dana Brakman Reiser, "Theorizing Forms for Social Enterprise," *Emory Law Journal* 62 (2013): 681; Alex Nicholls, "Institutionalizing Social Entrepreneurship in Regulatory Space: Reporting and Disclosure by Community

SEs are organizations that are driven line businesses,[35] but at the same time they are bound to pursue social goals by law and by their own articles of association.[36] SEs are then characterized by an entrepreneurial nature and a social dimension. The entrepreneurial nature of social enterprises is usually defined by the following five aspects: (1) a continuous and necessary economic activity producing goods and/or services of general interest; (2) an appropriate degree of financial and economic autonomy; (3) a significant level of economic and management risk; (4) the presence of paid work; (5) a market orientation. All these aspects imply that most of SEs' income has to derive from the market (services sold directly to users) or from contractual transactions with public authorities.[37]

Social enterprises would therefore be engaged in a wide range of different activities, which can be divided into two main areas: the work integration of disadvantaged people and the provision of welfare services.[38] Social enterprises performing work integration activities have been traditionally engaged with both public authorities and private companies to develop specific employment programs for people with disabilities.[39] As for health and welfare services, SEs may perform a wide range of activities: from traditional health and social care services, like almshouses or residential care homes, to more innovative services, such as those benefiting migrants.[40]

Interest Companies," *Accounting, Organizations and Society* 35, no. 4 (2010): 394–415; Simon Teasdale, "What's in a Name? Making Sense of Social Enterprise Discourses," *Public Policy and Administration* 27, no. 2 (2012): 99–119.

35 See: Raymond Dart, "Being "Business-Like" in a Nonprofit Organization: A Grounded and Inductive Typology," *Nonprofit and Voluntary Sector Quarterly* 33, no. 2 (2004): 290–310.

36 Cecilia Grieco, Laura Michelini, and Gennaro Iasevoli, "Measuring Value Creation in Social Enterprises: A Cluster Analysis of Social Impact Assessment Models," *Nonprofit and Voluntary Sector Quarterly* 44, no. 6 (2015): 1173–93.

37 See: European Parliament, Directorate General for Internal Policies, Policy Department C: Citizens' Rights and Constitutional Affairs, A European Statute for Social and Solidarity-Based Enterprise, 2017.

38 European Commission, *A Map of Social Enterprises and Their Eco-Systems in Europe*, Brussels 2015, 33.

39 Roy, Baker, and Kerr, "Conceptualising," 145.

40 Social enterprises "provide by-passes to health care as long as the law is officially respected," thus avoiding the insurgence of potentially dangerous cases not only for the beneficiaries but "also for the ethical legitimization of democratic states with portions of public opinion sensitive to human rights." Maurizio Ambrosini, "NGOs and Health Services for Irregular Immigrants in Italy: When the Protection of Human Rights Challenges the Laws," *Journal of*

In providing these services, social enterprises have gradually developed a definite and clear entrepreneurial dimension. This has made them reliable partners of local health authorities: in many MSs, public authorities entrust SEs with public functions and tasks particularly because of their governance, organizational structure and social purposes.[41]

4. Social Enterprises and the Provision of Services of General Interest (SGIs)

The modern role and importance of SEs is particularly clear in the European Union,[42] in which the economic and social spheres have been traditionally separated. Such a separation has allowed the MSs to develop their own culturally distinct social and welfare policies and continue with redistributive policies in tune with national preferences.[43] Yet, over time and due to market globalization, national health care systems have been exposed to EU economic law as providers of health care services and new markets have emerged. However, the EU internal market rule is proving neither flexible nor adequate when it comes to regulating the provision and supply of social and health care services.[44] Within this EU legal framework, welfare and health care services fall under the definition of "Services of General Interest" (SGIs).[45] These are mainly services that governments and local authorities acknowledge to benefit the community at large. Accordingly, SGIs are defined by the activities carried out and by the specific public goal they are

Immigrant & Refugee Studies 13, no. 2 (2015): 118. For discussion on the role of SEs in health care in the UK, see: Rachael Addicott, "Social Enterprise in Health Care," The King's Fund, 4 August 2011.

41 See: Bobby Macaulay et al., "Differentiating the Effect of Social Enterprise Activities on Health," *Social Science & Medicine* 200 (2018): 211–7.

42 For a glance of the fields of activity of social enterprises in Europe, see: European Commission, *Social Economy and Social Entrepreneurship, Social Europe Guide*, vol. 4, March 2013, 37.

43 See: Johan Van de Gronden and Erika Szyszczak, "Introducing Competition Principles into Health Care through EU Law and Policy: A Case Study of the Netherlands," *Medical Law Review* 22, no. 2 (2014): 238–54.

44 See: Wolf Sauter, "The Impact of EU Competition Law on National Healthcare Systems," *Tilburg Law School Legal Studies Research Paper Series*, no. 12 (2012): 1.

45 This definition is included in Section 16 of the European Treaty and it is widely dealt with in the White Paper on services of general interest drafted by the European Commission, Brussels, 12 May 2004 COM(2004) 374 final.

intended to achieve. In particular, these services are performed to ensure European individuals' fundamental rights, such as the right to health. This means that health care services must comply with certain strict requirements. Firstly, they are to be universal, meaning that all citizens are expected to be able to access them freely and to afford them. Secondly, these services are to be continuous, meaning that their interruption is forbidden on public grounds. Thirdly, SGIs are to respect certain valuable standards of quality. Finally, SGIs need to ensure an adequate level of users/patients' protection. Due to these characteristics of SGIs, MSs and the European institutions take on the responsibility to provide citizens with services that need to be effective, of quality, non-discriminatory and accessible.[46] It is noteworthy that SGIs are excluded from the internal market rule according to which all MSs are obliged to promote competition among economic operators. Such an exclusion makes it possible for SGIs not to be subject to privatization, liberalization or deregulation policies like others services. This exemption also favors the engagement of SEs in the delivery of this particular category of services. According to Directive 2006/123/EC, health care services are to be reserved to a number of regulated health professions in the Member State in which the services are provided. The Directive does not address the ways and the forms by which these services are organized and financed at the national level or whether the services are supplied by a public institution or a private organization. Insofar as health care services are aimed at accomplishing social cohesion and making fundamental rights enforceable, they should not fall within the scope of the internal market rule. This is the legal reason why EU law takes into account the specific tasks entrusted to the providers of these services.[47] Consequently, given the goals pursued and their organizational nature, SEs are often entrusted with the provision of SGIs, which also helps to enforce citizens' fundamental rights.

46 "In the Union, services of general interest remain essential for ensuring social and territorial cohesion and for the competitiveness of the European economy. Citizens[…] rightly expect to have access affordable high-quality services of general interest throughout the European Union." White Paper on services of general interest, 4.

47 European Commission, *Second Biennial Report on Social Services of General Interest*, Publications Office, 2011, SEC(2010) 1284.

5. Social Enterprises and The Right to Health

Citizens' fundamental rights are enshrined in the Charter of the Fundamental Rights of the European Union.[48] This includes the possibility of accessing a relatively wide range of services.[49] In this respect, Article 35 provides for a general right to health to be enjoyed by all individuals.[50] The circumstance that the right to health falls under the broad definition of human rights makes it part of the EU policy and no longer the obligation of just one Member State. EU law therefore provides for a general obligation not to violate fundamental rights (negative approach). At the same time, it also encourages both governments and nonprofit organizations to be committed to promoting the implementation of those rights according to the European Charter (positive approach).[51] In this perspective, the right to health aims to enhance social equity and solidarity within the European national, public and universal social security systems.[52] The accomplishment of such an aim is entrusted to a system of procedural rights, in which health authorities

48 The Charter was adopted in December 2000 in the framework of the Treaty of Nice. See: Steve Peers et al., eds., *The EU Charter of Fundamental Rights: A Commentary* (Oxford: Hart Publishing, 2014), 951–2.

49 After the ratification of the Treaty of Lisbon, some categories of social rights have undoubtedly become part of the EU law. See: Giovanni Maria Caruso, "Diritti sociali, risorse e istituzioni: automatismi economici e determinismo politico di un sistema complesso," federalismi.it, no. 4 (2016): 12, accessed May 31, 2024, https://federalismi.it/nv14/articolo-documento.cfm?artid=31442. See also: Silvio Gambino, "Livello di protezione dei diritti fondamentali (fra diritto dell'Unione, convenzioni internazionali, costituzioni degli Stati membri) e dialogo fra le Corti. Effetti politici nel costituzionalismo interno ed europeo," federalismi.it, no. 13 (2014): 2, accessed April 28, 2024, https://www.federalismi.it/nv14/articolo-documento.cfm?artid=26474.

50 "Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities."

51 See: Giuseppe Palmisano, ed., *Making the Charter of Fundamental Rights a Living Instrument* (Leiden-Boston: Brill Nijhoff, 2014).

52 All EU Member States entitle almost all their citizens to health coverage. "Respect for human dignity demands that no one refrain from seeking medical care from fear of the consequences of doing so, and that no one suffer financial adversity as a result of having sought care. The moral foundations of universal coverage are as simple as that." See: Lawrence D. Brown, "Comparing Health Systems in Four Countries: Lessons for the United States," *American Journal of Public Health* 93, no. 1 (2003): 52. As far as the commitment of Member States to ensure an adequate level of health protection is concerned, see: European Commission,

retain a certain degree of autonomy and power.[53] However, their decision is subject to the scrutiny of the courts which, in turn, verify whether a decision taken by a public authority concerning the right to health is in accordance with national and EU laws.[54]

Within this legal framework, SEs carry out their activities to fulfil the principles that are set forth in the EU Charter of Fundamental Rights. In this respect, SEs are regarded as essential partners in performing and implementing all those welfare services, including health care services, that are necessary to fully ensure the right to health.

6. The Legal Recognition of SEs in Italy

In Italy, SEs have long thrived mostly through the legal form of social co-operative.[55] Yet, SGIs can also be pursued through foundations and associations, when these organizations are allowed to carry out economic activities. However, these nonprofit organizations were overtly prevented from doing so for a long time. The lack of a clear-cut legal definition of social enterprise, which could also encompass the possibility for associations and foundations to carry out entrepreneurial activities, triggered a public debate on the need for a law reform concerning SEs. In the early years of the twentieth century,

Expert Panel on Effective Ways of Investing in Health (EXPH), *Access to Health Services in the European Union*, Brussels, 3 May 2016, 4.

53 See: Article 41, paragraph 1 of the EU Charter of Fundamental Rights. See also: CJEU Judgment of 26 February 2013, Åklagaren v. Hans Åkerberg Fransson, Case C-617/10, especially paragraph 21, where the European judges stated as follows: "Since the fundamental rights guaranteed by the Charter must therefore be complied with where national legislation falls within the scope of European Union law, situations cannot exist which are covered in that way by European Union law without those fundamental rights being applicable. The applicability of European Union law entails applicability of the fundamental rights guaranteed by the Charter."

54 Christopher Newdick, "Citizenship, Free Movement and Health Care: Cementing Individual Rights by Corroding Social Solidarity," *Common Market Law Review* 43, no. 6 (2006): 1653.

55 The 1991 Social Co-operatives Act has provided for a special co-operative form through they can create job opportunities for their members and provide welfare services to local communities. In this respect, social co-ops are capable of transforming the traditional internal, mutual character of co-operative societies into positive, economic and social externalities. See: Giulia Galera, "Social and Solidarity Co-operatives. An International Perspective," in *The Oxford Handbook of Mutual, Co-operative, and Co-owned Business*, eds. Jonathan Michie, Joseph R. Blasi, and Carlo Borzaga (Oxford: Oxford University Press, 2017), 170–81.

three different legislative proposals to improve the legal framework relating to SEs were discussed. The first proposal aimed at amending the section of the 1942 Civil Code concerning foundations and associations. According to this proposal, these nonprofit organizations should have then also been allowed to carry out economic activities in order to pursue their social missions. The second option intended to improve the law on corporations so that their purposes also encompassed the pursuit of social aims. Finally, the third proposal was aimed at introducing a cross-cutting legal status that should have allowed for both nonprofit organizations and companies to adopt the legal form of a social enterprise. This inclusive approach to SEs became the legal content of the 2006 Social Enterprises Act. Accordingly, associations, foundations, solidarity co-operatives and companies could be incorporated as a social enterprise upon complying with some legal requirements. In particular, SEs could not distribute any profit among their stakeholders, members, or directors. The 2006 Act also prohibited for-profit companies and public authorities from both exerting any influence in the decision-making process of SEs and from sitting on their boards of directors. Additionally, the Act did not provide for any tax benefits for SEs, which would have been expected as a natural legal provision to be granted according to the specific goals that SEs were to pursue.

The non-distribution constraint, the lack of a tax benefit package and the prohibition on the participation of public authorities and private companies in SEs were regarded as significant hindrances in the development of SEs. Ten years on, a comprehensive reform act, namely the 2017 Third Sector Organisations Reform Act has included a specific regulation on SEs to overcome the previous legal and organisational pattern. The 2017 Social Enterprises Reform Act reaffirms he legal notion of an enterprise whose legitimacy is to pursue a social aim and to carry out services of general interest. The 2017 Act provides for an innovative dimension of SEs, which can be identified in at least three aspects. The first aspect relates to the governance model of the organizations that intend to adopt the social enterprise form. The second aspect is the specific public interest goals that SEs are called upon to achieve. Thirdly, social enterprises are allowed to distribute profits to a limited extent. In terms of governance, SEs must involve different stakeholders in the decision-making process. The 2017 Act considers co-management and the multi-stakeholder dimension as essential features

of social enterprises.[56] This involvement is not only provided for in the Act, but must also be implemented through some specific provisions in the SEs' articles of association. Accordingly, workers and all the other stakeholders must find their own way of being heard, consulted and called upon to vote, especially when the decisions to be taken affect work conditions and the quality of goods and services. The internal organizational process by which SEs carry out their activities is then recognized by the Italian legal system as a distinctive characteristic of these legal forms. As regards the general interest goals, Section 2 of the 2017 Act lists as many as twenty-two (22) different areas of activity to be performed by SEs, from health care to social tourism. This choice is to be read in the light of the Italian Government's intention to entrust SEs with the performance of almost all activities that may have a significant impact on local communities.[57] Finally, as opposed to the 2006 Act, the 2017 Social Enterprises Reform Act has breached the non-distribution constraint "taboo." Consequently, like in other MSs, also Italian SEs are potentially appealing to investors that might be willing to support their activities and services.[58]

The 2017 Social Enterprises Reform Act made it possible to overcome the traditional divorce between efficiency and solidarity, and between effectiveness and ideal motivations. This Act strikes a balance between two constitutional rights: on the one hand, it strengthens the importance of solidarity as a characteristic of SEs; on the other hand, it recognizes individuals' freedom to set up entrepreneurial organizations.[59] However, the

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56 On this issue, see: Zoe Adams and Simon Deakin, "Enterprise Form, Participation, and Performance in Mutuals and Co-operatives," in *The Oxford Handbook of Mutual, Co- operative, and Co-owned Business*, eds. Jonathan Michie, Joseph R. Blasi, and Carlo Borzaga (Oxford: Oxford University Press, 2017), 228–33.

57 In this respect, the Italian Parliament has acted in line with the approach of the European institutions. See: Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Social Business Initiative. Creating a favourable climate for social enterprises, key stakeholders in the social economy and innovation, Brussels, 25 October 2011 (COM(2011) 682 final.

58 In the European economic and legal systems, where social enterprises can distribute profits only to a certain given extent, these organizations have developed. See: Fici, "Funzione e modelli di disciplina," 314–5.

59 This approach is clearly rooted in Section 41 of the Italian Constitution, which provides for freedom of private enterprise. See: Fabio Cintioli, "L'art. 41 della Costituzione tra il paradosso della libertà di concorrenza e il 'diritto della crisi'," Astrid-online, accessed May 15, 2024, https://www.

distinguishing nature of this Act lies in its ultimate purpose. It is aimed to increase and enforce individuals' social and civil rights.[60] In this respect, social aims and activities of general interest warrant the tax deductions granted to this particular typology of nonprofit organizations. In particular, the tax benefits include a "tax-free" area for any profit that is re-invested in the organization's activities.

Overall, the 2017 Act provides for an enabling legal and institutional framework, which is intended to favor the development of SEs in Italy and to nudge their performance and their development as economic and social operators. At the same time, the Act respects the different legal forms under which SEs may carry out their activities. This approach helps to overcome the differences between the legal entities that have long defined the Italian legal system for nonprofit organizations, thus making them leave their historical unproductive role.

7. Some Concluding Remarks

The article sought to prove that SEs are legally recognized as independent health care providers. Through their entrepreneurial organization, SEs have developed a specific multi-stakeholder character and a democratic structure

astrid-online.it/static/upload/protected/Cint/Cintioli-F_Incontro_fondazione-Magna-Carta_15_06_10.pdf; Giuseppe Di Gaspare, "Costituzionalizzazione simbolica e decostituzionalizzazione di fatto dell'articolo 41 della Costituzione," Amministrazione in Cammino, May 3, 2011, accessed May 2, 2024, https://www.amministrazioneincammino.luiss.it/2011/05/03/costituzionalizzazione-simbolica-e-decostituzionalizzazione-di-fatto-dell%E2%80%99articolo-41-della-costituzione-2/; Ignazio Musu, "Gli aspetti economici della Costituzione italiana: è superato l'art. 41?," accessed April 28, 2024, https://www.astrid-online.it/static/upload/protected/MUSU/MUSU_art-41.pdf; Roberto Romei, "Chi ha paura dell'art. 41 Cost.?," in *Nelmerito*, June 25, 2010; Filippo Zatti, "Riflessioni sull'art. 41 Cost.: la libertà di iniziativa economica privata tra progetti di riforma costituzionale, utilità sociale, principio di concorrenza e delegificazione," Forum di Quaderni Costituzionali – Rassegna, no. 8 (2012): 1–18.

60 This commendable horizon for SEs must be confronted with the reduction of public funds for welfare services, which defines the Italian health care system as well as many European Member States. See: Renato Balduzzi, "Livelli essenziali e risorse disponibili: la sanità come paradigma," in *La tutela della salute tra garanzie degli utenti ed esigenze di bilancio*, eds. Carlo Bottari and Fabio A. Roversi Monaco (Rimini: Maggioli, 2012), 88. See also: Michele Belletti, "I 'livelli essenziali delle prestazioni' alla prova del 'coordinamento della finanza pubblica'. Alla ricerca della 'perequazione' perduta," in *L'erogazione della prestazione medica tra diritto alla salute, principio di autodeterminazione e gestione ottimale delle risorse sanitarie*, ed. Michele Sesta (Rimini: Maggioli, 2014), Part I, First Section, Chapter 4.

of their governing boards, which are common to almost all European welfare and legal systems. All of these are factors that give SEs certain specific comparative advantages and open up wider possibilities for action than the traditional non-distribution constraint.

Public support for SEs consists less of tax relief than of the recognition and consistent definition of legal forms, especially those adapted to the management of social activities on business principles.

SEs can also help create new job opportunities and primary employment in the sector of personal and social care services despite the limited availability of public resources. They can attract private resources, such as capital investments, donations and payments by service users. The particular areas in which SEs are engaged could boost competition among different kinds of organizations providing health care services. SEs also contribute to develop new products, new productive processes, new relationships with users and patients and, accordingly, new services. One of the chief advantages of SEs is their ability to attract not only workers and volunteers but also investors who are ethically motivated and not exclusively interested in monetary rewards.

Several European MSs and the European Union itself have already taken some steps to promote and regulate SEs. In this respect, the 2017 Social Enterprises Reform Act may prove innovative at the European level. The combination of legal certainty regarding the legal form, the involvement of different stakeholders and the granting of a set of tax benefits geared towards the pursuit of a wide range of services of general interest may be construed as a regulation that could actually represent a valuable benchmark for other national jurisdictions.

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Normative Approach to Workers' Mental Well-Being in the Digital Era

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Keywords:
labor rights,
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psychosocial risks,
right to disconnect

Abstract: The paper aims to provide theoretical insights and explore the comparative legal practice of approaching mental health and well-being at the workplace by applying legal normative and comparative methods in a digitalized world of work. In this regard, subordination vs autonomy needs to be considered as a starting theoretical point accompanied by an overview of comparative legal approaches that have recently introduced some novel legal mechanisms, such as the right to disconnect to deal better with the exercise of fundamental labor rights. Additionally, introducing a psychosocial risk management model in occupational health and safety could significantly improve workers' mental health and well-being in the digital age. Therefore, the proactive, holistic, and integrated approach to workers' rights and status in the digital environment must be analyzed by exploring the bounding point between organizational management views on the subject and labor law standpoints.

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1. Introduction

In the post-pandemic period and with the ongoing digital revolution, mental health became a major public health concern, as well as an issue frequently addressed in recent studies of organizational and human resource management, social psychology, and law. Most studies concern organizational management, pointing to the psychological contract and its impact on job satisfaction and the mental well-being of workers.[1] However, the significance of employment contracts in determining (decent) working conditions in a changed work environment has been poorly addressed by academics. Additionally, the similarities and differences between so-called psychological (work) contracts and (legal-normative) employment contracts have not received much attention from researchers studying labor law and human resources. On the other side, labor law scholars are engaged in the constant debate about the future of Labor law as a legal discipline in the changed world of work, where the precise line between work and private life has been fading away with the development of informational and communicational technologies impacting on workers mental health and well-being in general. Finally, the question of introducing novel, adjusting mechanisms to address these challenges is posed.

After the introduction in the first section of the paper, the theoretical framework of mental well-being at the workplace has been presented from an organizational, i.e. managerial, and legal perspective. The second part deals with the link between psychological and employment contracts by exploring their nature and examining the conceptual possibilities of integrating those two into the mental health management model at the (digital) workplaces. The last section points to contemporary solutions, i.e. emerging

[1] See: Sabine Pohl, Françoise Bertrand and Roland Pepermans, "Relationship between Psychological Contract Breach and Organizational Affective and Normative Commitment: The Role of Perceived Organizational and Supervisory Support," *Le travail humain* 83, no. 3 (2020): 269–84; Yasir Mansoor Kundi et al., "Employee Psychological Well-Being and Job Performance: Exploring Mediating and Moderating Mechanisms," *International Journal of Organizational Analysis* 29, no. 3 (2021): 736–54; Mareike Reimann and Jakob Guzy, "Psychological Contract Breach and Employee Health: The Relevance of Unmet Obligations for Mental and Physical Health," *Journal of Work and Organizational Psychology* 22 (2017): 1–17; Yannick Griep et al., "How Psychological Contract Breach Affects Long-Term Mental and Physical Health: The Longitudinal Role of Effort–Reward Imbalance," *Applied Psychology: Health and Well-Being* 13, no. 2 (2021): 263–81.

labor law and employers' (internal) policy mechanisms that could contribute to mental well-being. In this regard, the right-to-disconnect concept introduced in various legal systems and psychosocial risk management systems supported through occupational health and safety regulation have been frequently addressed.

2. Mental Well-Being Concept – Organizational and Legal Approach

According to the World Health Organization (WHO) definition, mental health is a state of mental well-being that enables people to cope with the stresses of life, realize their abilities, learn well and work well, and contribute to their community. At any time, a diverse set of individual, family, community, and structural factors may combine to protect or undermine mental health. Although most people are resilient, people who are exposed to adverse circumstances – including poverty, violence, disability, and inequality – are at higher risk of developing a mental health condition.[2] Emergencies such as armed conflicts, natural disasters, and other humanitarian crises exacerbate the risk of mental health conditions. Nearly all people affected by these emergencies will experience psychological distress, with one in five likely to have a mental disorder such as depression, anxiety, post-traumatic stress disorder, bipolar disorder, or schizophrenia. These risks are heightened in older people and marginalized groups.[3]

Based on mental health policy results and service research and evaluation of mental health reform, in 2004, the WHO issued recommendations in several countries on the organization of mental health services entitled *Mental Health Policy and Service Guidance Package*.[4] This document provides practical information to help countries improve the mental health of their citizens. The recommendations aim to help deliver integrated services, address the various needs of people with mental disabilities, and define

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2 WHO, "Mental Health," 2024, accessed February 22, 2024, https://www.who.int/health-topics/mental-health#tab=tab_1.

3 WHO, "Ensuring a Coordinated and Effective Mental Health Response in Emergencies," accessed January 13, 2024, https://www.who.int/activities/ensuring-a-coordinated-and-effective-mental-health-response-in-emergencies.

4 *Mental Health Policy, Plans and Programmes. Mental Health Policy and Service Guidance Package* (World Health Organization, 2004) accessed January 13, 2024, https://iris.who.int/bitstream/handle/10665/42948/9241546468.pdf?sequence=1.

some of the key organizing principles of mental health services.[5] The WHO proposed a multi-level model for the organization of mental health services using a pyramid framework.[6]

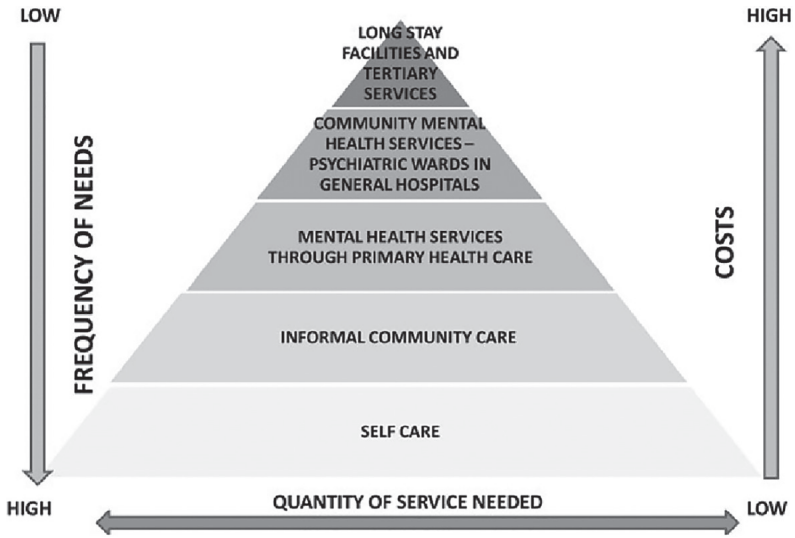

Figure 1. Pyramid framework for the organization of mental health services, WHO (Antonio Lora et al., "Information for Mental Health Systems: An Instrument for Policy-Making and System Service Quality," *Epidemiology and Psychiatric Sciences* 26, no. 4 (2017): 383–94).

Although it is broader in terms of coverage of the persons it refers to, the United Nations Convention on the Rights of Persons with Disabilities (2006)[7] is also relevant for people with mental disabilities and their rights.

5 Ibid.

6 Angelo Barbato et al., "Access to Mental Health Care in Europe – Consensus Paper" (EU Compass for Action on Mental Health and Well-being, 2016), 1–38.

7 UN (2006) Convention on the rights of persons with disabilities, A/RES/61/106, signed 30 March 2007, effective 3 May 2008.

It covers the whole spectrum of rights important for life in the community of persons with disabilities (PWD), including the right to (decent) work. Article 27 prescribes that states parties recognize the right of PWD to work on an equal basis with others. This includes the right to the opportunity to earn a living by working freely chosen or accepted in a labor market and work environment that is open, inclusive, and accessible to PWD. States parties are obliged to safeguard and promote the realization of the right to work, including for those who acquire a disability in the course of employment, by taking appropriate steps.

When it comes to the European system of human rights protection, it includes a large number of instruments (mandatory and non-mandatory acts and mechanisms) that are important for people with mental disabilities: European Convention on Human Rights of the Council of Europe (1953),[8] and the body for supervising its implementation – the European Court of Human Rights; European Convention for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (2002);[9] European Social Charter[10] in the area of housing, health, education, employment, social and legal protection, free movement of persons, and non-discrimination; Charter of Fundamental Rights of the European Union (2000);[11] as well as Mental Health Declaration for Europe, Helsinki (2005).[12]

The Mental Health Declaration for Europe (2005) was the cornerstone of developing and reforming European mental health policy. In the Declaration, all European ministers of health confirmed that mental health is a priority area; they recognized the need for evidence-based mental health policies, defined a broad framework of these policies, undertook to develop, implement and strengthen such policies, and proposed twelve

8 CE (1953) European Convention on Human Rights (ECHR), Rome, 4 June 1950.

9 CE (2002) European Convention for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment, European Treaty Series – No. 126, Text amended according to the provisions of Protocols No. 1 (ETS No. 151) and No. 2 (ETS No. 152) which entered into force on 1 March 2002.

10 CE (1996) European Social Charter, European Treaty Series – No. 163; ETS163 – European Social Charter (Revised), 3 May 1996.

11 EU (2000) Charter of Fundamental Rights of the European Union, 2000/C364/01, 7 December 2000.

12 WHO (2005) Mental Health Declaration for Europe, EUR/04/5047810/6, 14 January 2005, Helsinki.

areas of activity to be implemented by 2010. These areas include promoting the mental well-being of the population as a whole by measures that aim to create awareness and positive change for individuals and families, communities and civil society, educational and working environments, and governments and national agencies; designing recruitment, education, and training programmes to create a sufficient and competent multidisciplinary workforce. One of the responsibilities of the states signatories is to prevent risk factors where they occur, for instance, by supporting the development of working environments conducive to mental health and creating incentives for providing support at work or the earliest return for those who have recovered from mental health problems.

The WHO recently issued the *WHO European Framework for Action on Mental Health 2021–2025*.[13] Among other things, the document emphasizes mental health in the workplace. It includes the recommendation that programmes to promote mental well-being and prevent mental health conditions in the workplace, such as adaptation to new working modalities, management of stress, and prevention of substance abuse, should be developed and their implementation supported.

On June 7, 2023, the Commission adopted the Communication on a comprehensive approach to mental health (2023),[14] which will help Member States and stakeholders take swift action to deal with mental health challenges. It recognizes that mental health is about more than just health and strongly involves areas such as education, digitalization, employment and labor, research, urban development, environment, and climate.

3. Psychological vs Employment Contract – Conceptualization Issues

Some labor law scholars argue for the introduction of so-called labor quality law emerging under the influence of the Fourth Industrial Revolution and considering the qualitative aspects of employment relationships such as equal opportunities at the workplace, personal flexibility and autonomy, and

[13] WHO Regional Office for Europe, "WHO European Framework for Action on Mental Health 2021–2025," 2022, accessed January 16, 2024, https://www.who.int/europe/publications/i/item/9789289057813.

[14] EU (2023) Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on a comprehensive approach to mental health, COM(2023) 298 final, 7 June 2023.

health (mental and physical) well-being at work by placing the worker/human in front and at the centre of socio-economic transition and reconceptualization of labor law.[15] Having said that, it is worth mentioning that prevailing views regarding contemporary trends in labor unionization in terms of the impact on workers' rights stress that the core aim of modern labor law is "to satisfy the worker's need for meaningful protection and participation in the workplace, rather than simply to preserve the institutional formats through which those functions have traditionally been performed."[16]

Other academics also highlight the changing labor relations in the digital age as the main triggering mechanism for the foundation model of modern labor law, arguing the functional approach to changed working and management practices, work environment, and consequently employment relationship model in the national context.[17] Modern labor law appears to be developing in a direction that places an individual worker's needs, expectations, and perceptions at the centre of the employment relationship. Consequently, the non-legal, i.e. psychological, elements of that relationship must be analyzed along with the legal ones.

The traditional objective of labor law is regulating labor relations, primarily the relationship between employer and employee[18] based on the employment contract. Historically, both in common law and European-continental legal systems, the conceptualization of the employment contract is highly complex considering its hybrid nature, i.e. civil/contractual and public law elements embedded in the legal (employment) relationship comprising both the individual/business of laissez-faire and collective/public interests of the welfare state doctrines.[19] In essence, there is a common idea that cooperation and trust are cornerstones of any employment relationship;

15 Marc De Vos, "Work 4.0 and the Future of Labour Law," July 2018, https://ssrn.com/abstract=3217834.

16 David Doorey, "Reflecting Back on the Future of Labour Law," *University of Toronto Law Journal* 71, no. 2 (spring 2021): 165–206.

17 Marianne Jenum Hotvedt and Natalie Videbæk Munkholm, "Labour Law in the Future of Work" (Nordic future of work project 2017–2020 Working paper 1, Fafo paper (2019):06).

18 Today, considering the flexible employment arrangements and non-unified concept of "employee," the term worker is more adequate and will be used in this article.

19 Simon Deakin, "The Contract of Employment: A Study in Legal Evolution. Working Paper No. 203" (University of Cambridge: ESRC Centre for Business Research, 2001).

thus, in a broad context, the employment contract represents the "social form of cooperation" between two parties where one (worker) is considered as the weaker party and needs special/additional legal protection.[20]

However, societal, economic, technological, and demographic changes undoubtedly call for flexibility in conceptualization and the specific conceptual "openness" to adaptation and evolution of an employment relationship in time. This approach has been supported by legislation practice in most legal systems, in which statutes, i.e., labor acts/codes, rarely explicitly define an employment contract and/or employment relationship, leaving the court to determine by using specific tests and indicators.[21] From a labor law perspective, the main indicators, i.e. elements and characteristics, of an employment relationship are a contract-based relation, voluntary-based work, wage/remuneration, and workers' subordination to employers' power. Labor law generally defines an employment contract as a written agreement between employer and worker about terms and conditions of employment, mainly considered an economic exchange between parties but with certain social justice elements and determined legal sanctions in terms of violation.[22]

Thus, the lack of a specific normative definition of employment contract in most jurisdictions, accompanied by vagueness in legal doctrine and inconsistent judicial practices, are all factors that could significantly impact workers' status and enjoyment of fundamental rights, particularly in a time of profound technological changes. However, apart from that, legal studies on this matter are lacking. In the European domain, there is vagueness in approaching the employment contract in legal doctrine. As has been said, most legislation does not precisely define the employment contract or employment relationship.[23] For instance, the French Labour Code does not

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20 Jenum Hotvedt and Videbæk Munkholm, "Labour Law."

21 Ibid.

22 John W. Budd and Devasheesh P. Bhave, "The Employment Relationship: Key Elements, Alternative Frames of Reference, and Implications for HRM," in *The SAGE Handbook of Human Resource Management*, 2nd ed., eds. Adrian Wilkinson et al. (Singapure: SAGE Publications Ltd, 2019), 41–64.

23 Georges Cavalier and Robert Upex, "The Concept of Employment Contract in European Union Private Law," *The International and Comparative Law Quarterly* 55, no. 3 (July 2006): 587–608.

provide a universal definition of an employment contract. However, scholars are consistent in their views that the employment contract is a bilateral agreement between employer and employee where the employee agrees to undertake personal work under the supervision of the employer, i.e. putting themselves in a subordinate position and, in return, they are entitled to payment/salary and protection at the workplace.[24] On the other hand, German law (*Bürgerliches Gesetzbuch: BGB, Section 611a*)[25] states that:

> By the employment contract, the employee is obliged to perform work in the service of another; such work being tied to instructions and determined by others; and to do so in a relationship of personal dependency (...). In this context, the degree of personal dependency will be determined according to the specific nature of the activity concerned.

The main criteria for the determination are the factual and legal dependence of a person engaged in any form of work, meaning that the principle of subordination is crucial for the qualification.[26]

Although changes in employment and labor caused by the digital revolution questioned subordination as the main characteristic of an employment relationship, the core distinguishing criteria between employment contracts and other civil/commercial contracts is the worker's subordination to the employer's power.[27] Thus, for instance, Spanish, Portuguese, and Italian labor laws specifically highlight the criteria of employee dependence on the employer in terms of obedience to the employer's managerial prerogatives.[28]

However, academics and policymakers have recently advocated the modification of the traditional concept of employment relationship based on the emergence of flexible forms of work arrangements in a digitalized world of work. Non-standard forms of employment (i.e. platform

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24 Ibid.

25 Bürgerliches Gesetzbuch: BGB, Section 611a, accessed March 11, 2024, https://www.gesetze-im-internet.de/bgb/__611a.html.

26 Cavalier and Upex, "The Concept of Employment Contract in European Union Private Law."

27 Judy Fudge, "Fragmenting Work and Fragmenting Organizations: The Contract of Employment and the Scope of Labour Regulation," *Osgoode Hall Law Journal* 44, no. 4 (2006): 609–48.

28 Felicia Rosioru, "The Changing Concept of Subordination," in *Recent Developments in a Labour Law*, ed. György Kiss (Budapest: Akadémiai Kiadó, 2013), 150–85.

work, economically dependent self-employment) blurred the boundaries between the traditional subordinate employment relationship and independent work, posing the question of reconceptualization of the subordination concept by "broadening the scope of labour-law protection to cover other less visibly subordinate labour relationships."[29] In the ongoing technological changes where the job tasks could be done under the principle "anytime and anywhere," the main managerial prerogatives of an employer became quite vague. Hence, the subordination became weaker while the workers' autonomy prevailed, striving to challenge the very foundation of the traditional employment relationship concept. Given the above, an improved concept/model of evolution and adaptation needs to be introduced by applying an integrated and holistic approach and considering all varieties of (digitalized) societal and employment relationships. In this regard, established ethical and cultural standards in the work environment and the subjective perception of an employee on work duties and rights need to be considered when approaching the modern concept of an employment relationship.

Having said that, in organizational and human resource management, the notion of psychological contract and the consequences of psychological contract breach (PCB) in terms of workers' status became widely explored, along with the effects of psychological contract breach on workers' mental health and well-being.[30] In this regard, the interconnectedness between psychological and employment contracts needs to be critically evaluated by exploring the theoretical and conceptual similarities and differences.

The concept of psychological contract dates back to the 1960s and is described mainly in organizational management literature as a relationship between employer and worker that considers the individual beliefs/expectations of parties concerned regarding reciprocal obligations of exchange.[31]

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29 Sanja Stojković Zlatanović and Ivana Ostojić, "Labour Law Status of Platform Workers – Between Autonomy and Subordination," in *Regional Law Review*, ed. Mario Reljanović (Belgrade: Institute of Comparative Law, 2021), 269–81.

30 See: Yueyuan Cheng, "The Effect of Psychological Contract Combined With Stress and Health on Employees' Management Behavior," *Frontiers in Psychology* 12, no. 10 (2021): 667302; Reimann and Guzy, "Psychological Contract Breach," 1–17.

31 Juan Herrera and Carlos De Las Heras-Rosas, "The Organizational Commitment in the Company and Its Relationship with the Psychological Contract," *Frontiers in Psychology* 11, no. 609211 (January 2021).

The psychological contract is an unwritten agreement containing both explicit promises and implicit expectations of parties involved in a (legal) employment relationship. Besides the implicit expectations, the subjective perception of the relationship is the key difference between a psychological contract and an employment contract.[32] From an organizational management perspective, the consequences of a PCB are related to trust and loyalty issues, job satisfaction, organization commitments, and an individual worker's mental and physical health and well-being.[33]

It could be noted that the consequences of PCB impact not only the worker's health status but also the business interests and economic goals of an employer, considering the effects on job performance, workers' productivity, and efficiency of a company. Given the above, the employer's best (economic) interest is to build a relationship that goes beyond the contractual obligations of the employment contract, particularly considering the definition of the psychological contract expressed in organizational management literature as a "tacit agreement between a company and workers to maintain the legal relationship between them."[34] Therefore, it could be argued that the psychological contract has been naturally embedded into an employment contract. It also means that the unwritten part of any employment contract that grounds the trust and loyalty between parties and creates mutual expectations of contractual obligation fulfilment as a basis for entering into the employment relationship by concluding the employment contract is actually – a psychological contract.

While most of the conducted studies on organizational management deal with the PCB and its impact on job performance, job satisfaction, and organizational commitment,[35] the empirical studies that analyzed health-related issues of PCB were mainly limited to a particular group of employees, i.e. military and police officers.[36] On the other hand, it is worth mentioning that Reimann & Guzy (2017) investigated the consequences of PCB on workers' mental and physical health engaged in various industrial

32 Kate McInnis, "Psychological Contracts in the Workplace: A Mixed Methods Design Project" (PhD diss., Western University, 2012).

33 Ibid.

34 Cheng, "The Effect of Psychological Contract."

35 Herrera and De Las Heras-Rosas, "The Organizational Commitment."

36 Reimann and Guzy, "Psychological Contract Breach," 1–17.

sectors and found that PCB mostly affects mental health and well-being while having only indirect effects on physical health. Furthermore, evidence from various studies reveals a positive correlation between PCB and mental well-being indicators such as anxiety, depression, and burnout syndrome.[37] Therefore, Reimann & Guzy (2017) argued that PCB should be recognized as a specific psychosocial work stressor.

Having this in mind, we could pose a question of interconnections between PCB as a psychosocial work stressor and psychosocial risks and hazards that have come into the focus of European policymakers in terms of introducing the psychosocial risks management model as a novel mechanism of occupational safety and health law (OSH). Psychosocial hazards at work are defined as factors that negatively influence a worker's mental and physical health and well-being. In contrast, psychosocial risks comprise the interactions between work organization and management practices, on the one hand, and individual, subjective perceptions, expectations, and beliefs regarding worker's status and consequently working conditions, on the other hand, that could impact psychophysical health.[38] In the last decades, the focus of European OSH policymakers and legislators has shifted from the risk assessment model to the risk management model, emphasizing the emerging psychosocial hazards and risks of the digital environment as a main priority.[39] This is another argument that supports integrating the organizational management approach into the labor law framework, meaning the recognition of PCB as an emerging psychosocial risk in a digitalized world of work. Given the above, the psychological contract must also be considered when it comes to modernizing the employment relationship model.

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37 Griep et al., "How Psychological Contract Breach," 263–81.

38 Sergio Lavicoli and Christina Di Tecco, "The Management of Psychosocial Risks at Work: State of the Art and Future Perspectives," *La Medicina del Lavoro* 111, no. 5 (2020): 335–50.

39 Christina Di Tecco, Bernadetta Persechino, and Sergio Lavicoli, "Psychosocial Risks in the Changing World of Work: Moving from the Risk Assessment Culture to the Management of Opportunities," *La Medicina del Lavoro* 114, no. 2 (2023): e2023013. https://doi.org/10.23749/mdl.v114i2.14362.

4. Emerging Labor-Law and Policy Mechanisms of Mental Health Protection – A European and Comparative Overview

Mental health protection in terms of labor become a topic that has been given more and more attention at the European Union level, particularly in the post-pandemic period and with the ongoing digital revolution. Although the EU and national policymakers joined forces to address the issues of mental health and well-being deterioration that emerged with the Fourth Industrial Revolution, the legal theory and doctrine still lag far behind in approaching the subject.

In this regard, it is worth mentioning that Bielby (2019) [40] defines mental health vulnerability as a "subjective-evaluative well-being" that arises from a psychological and social perception of an individual and self-resilience expressed in a particular environment that also includes a work environment. By suggesting the implementation of the legal theory of the novel concept of mental vulnerability, the author practically stands for the idea of "proactive vulnerability management" and state responsibility to address the issues of mental health challenges in neoliberal societies.[41] This doctrinal standpoint could be a valuable basis for current policy initiatives at the EU level for broader collaboration between social partners and governments to create a healthier psychosocial safety work climate by approaching the concept of psychosocial risk from workers' individual/subjective perspectives.

When it comes to the EU policy initiatives on mental health protection as part of OSH, the most recent document adopted is the European Commission's Strategic Framework on Health and Safety at Work 2021–2027,[42] which calls for collaboration between social partners and Member States to deal better with emerging changes (digital, green, and demographic transitions) by improving prevention of workplace accidents and illnesses while coping with new health risks and hazards, particularly emphasizing psychosocial risks. A psychosocial hazard that negatively affects mental health

40 Phil Bielby, "Not 'Us' and 'Them': Towards a Normative Legal Theory of Mental Health Vulnerability," *International Journal of Law in Context* 15, no. 1 (2019): 51–67.

41 Ibid.

42 EU (2021) EU Strategic Framework on Health and Safety at Work 2021–2027, DG EMPL – B3, Ref. Ares(2020)608950, 29 October 2020.

and was specifically addressed in this document is work-related stress. On the other hand, emerging psychosocial risks, including permanent connectivity, lack of social interactions, and imbalance between work and private life, are quoted as important to consider in risk assessment and management procedures at the workplace.

A more specific EU policy approach to mental health in the era of digitalization has been made by adoption of the European Parliament resolution of 5 July 2022 on mental health in the digital world of work,[43] emphasizing the necessity to broaden the definition of health and safety at the workplace to include mental health concerns, particularly work-related stress, burnout, depression, and anxiety, as well as harassment, violence, and discrimination. The reference to mental health in the digital transition points to a proactive, preventive, protective and both individual and collective approach to mental health and well-being with a focus on work-related psychosocial risks of constant connectivity, work-life imbalance, social isolation, and AI misuse. Furthermore, gender issues, intergenerational solidarity, and minority protection must be addressed in the national policy and legal documents. The resolution calls for improvements in preventive measures of OSH management at the digital workplaces, prioritizing education and raising awareness of poor mental health through developing psychosocial training programmes and creating local or regional mediation services for emerging psychosocial risks.

To address the emerging psychosocial risks, particularly the constant connectivity, the European Parliament resolution on the right to disconnect[44] has been suggested as a follow-up mechanism. The right to disconnect is defined as a worker's right not to be available to the employer via digital devices after working hours without posing any restrictions or sanctions for the worker.[45] At the EU level, the introduction of the right to disconnect as a special/additional mechanism of enjoyment of the right to rest and leisure, as a fundamental labor right, to protect health and safety takes

43 EU (2022) European Parliament resolution of 5 July 2022 on mental health in the digital world of work, 2021/2098(INI), C 47/63, 7 February 2023.

44 EU (2021) European Parliament resolution of 21 January 2021 with recommendations to the Commission on the right to disconnect, 2019/2181(INL), C 456/161, 10 November 2021.

45 Marta Urbane, "The Future of the Employee's Right to Disconnect in the European Union and Latvia," *Human Factors, Business Management and Society* 56 (2022): 329–35.

the form of a legislative initiative. However, policymakers and academics have not reached a consensus regarding its legal nature – a novel right or additional policy mechanism for enforcing fundamental labor rights. However, among labor law scholars, the right to disconnect has not been considered a novel right but rather a policy mechanism for enforcing the right to rest and leisure in terms of mental health and well-being protection. Accordingly, the right to disconnect needs to be evaluated in the context of an additional psychosocial risk assessment and management instrument that emerged with workplace digitalization.[46]

On the other hand, psychosocial risks and the OSH management system at the level of the employer have been traditionally regulated by the OSH Framework Directive 89/391/EEC,[47] which determines the employer's obligation to assess all types of risks at the workplace and establish the preventive and protective OSH procedures. These provisions could also be interpreted to include the new, emerging psychosocial risks in a digital environment. However, OSH regulations have substantial national dimensions and specificities.

As a pioneering EU country, France introduced the right to disconnect through the El Khomri law of 2016 for workers in public and private sectors but did not determine the content and scope of the right, leaving it to the social partners to negotiate, nor it did statutorily recognize other types of psychosocial risks in mental health protection except bulling. Nevertheless, Law n°2002–73 of 17 January 2002 sets out the employer's obligation to protect mental health.[48] A certain step forward in France's OSH legislation and approach to mental health at the workplace was the adoption of Law n°2021–1018 of 2 August 2021, aiming to prevent workers' overload by introducing the right to warning and withdrawal.[49] However, emerging psychosocial risks and management instruments are the subject

46 Sanja Stojković Zlatanović and Milena Škobo, "The 'Twilight' of Health, Safety, and Well-being of Workers in the Digital Era – Shaping the Right to Disconnect," *Journal of Work Health and Safery Regulation* 2, no. 2 (2023): 129–44, https://doi.org/10.57523/jaohlev.oa.23-003.

47 EU (1989) Council Directive on the introduction of measures to encourage improvements in the safety and health of workers at work, 89/391/EEC, L 183, 29 June 1989, P. 0001–0008.

48 Jean-Paul Dautel, "Psychosocial Risks in France" (Presentation), accessed January 26, 2024, https://www.etui.org/sites/default/files/2022-02/P3_JP_Dautel_PSR_in_France_2022_0.pdf.

49 Ibid.

of collective bargaining, such as the above-mentioned right to disconnect, work-life balance, and exercise of the right to expression.

In the context of the digital work environment, introducing so-called cyberbullying as a psychosocial risk could be valuable for workers' (mental) health protection. For example, in some provinces of Canada, labor statutes have been amended to broaden the definition of health and safety to include bullying at work under the definition of "psychological harassment," where the court can impose a "protection order," which involves a restriction of physical contact or even online communication.[50] Referring to "online communication" potentially means protection against cyberbullying at the workplace as an emerging psychosocial risk in a digital environment, which represents an example of good practice in this field.

On the other hand, Italy introduced a statutory limited the application of the right to disconnect to remote workers and delegated the power to social partners to determine the scope and content of the right, as France did.[51] Moreover, in terms of psychosocial risk assessment and management, Italy, in Legislative Decree 81/08, approached the issue by implementing the provisions of the OSH Framework Directive 89/391/EEC, setting out the employer's obligation to assess all risks at the workplace, including those related to stress at work.[52] The Italian legislator apparently focused solely on work-related stress, while other psychosocial risks were neglected. Nevertheless, in January 2021, Italy ratified the International Labour Organization Convention No. 190 concerning eliminating violence and harassment in the world of work[53] and included these risks in the assessment and management procedure.

Finally, like France and Italy, Spain has adopted special legislation on the right to disconnect, approaching this right as both a civil privacy right in the Data Protection Act (2018) and a labor right in Law 10/2021 on

50 Bettina West et al., "Cyberbullying at Work: In Search of Effective Guidance," *Laws* 3, no. 3 (2014): 598–617.

51 Dima Luminiţa and Alex Högback, *Legislating a Right to Disconnect* (București: Friedrich-Ebert-Stiftung, 2020).

52 Di Tecco, Persechino, and Lavicoli, "Psychosocial Risks in the Changing World of Work."

53 Ibid.

remote work.[54] The legislation regarding different types of emerging psychosocial risks has not been adopted; however, workplace harassment was determined as a serious infringement.[55] In terms of psychosocial risks in a digital environment, it is important to note that Spain set out the obligation for all employers to evaluate the psychosocial risks related to the usage of information and communications technologies by Law 31/1995, of 8 November 1995, while concrete preventive measures in OSH regarding remote work and teleworking have been determined by Law 10/2021 on remote work.[56] Law 10/2021 on remote work obligates employers to assess all risks of teleworking, particularly psychosocial, organizational, and ergonomic, such as light, musculoskeletal pain, or mental and physical fatigue.[57]

Considering the examples of European countries that are pioneering the right to disconnect as a novel mechanism to cope with emerging psychosocial risks and mental health protection in a digital era, one might infer that the legislators continue to be inconsistent and unclear regarding the scope and content of this right by transferring the subject to social partners to negotiate. On the other hand, collective bargaining in this field is deficient, while employers/companies are unaware of mental health deterioration and implications to business interests, such as lower efficiency of workers, absenteeism, and finally, productivity of the company.[58] Therefore, it seems that legal doctrine and theory need to focus on the reconceptualization of traditional labor law institutions by reshaping labor rights in response to a changed world of work and approaching the subject in a multidisciplinary, proactive, holistic, and integrated manner.

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54 Loïc Lerouge and Francisco Trujillo Pons, "Contribution to the Study on the 'Right to Disconnect' from Work. Are France and Spain Examples for Other Countries and EU Law?," *European Labour Law Journal* 13, no. 2 (2022): 450–65.

55 Francesko Chirico et al., "Psychosocial Risk Prevention in a Global Occupational Health Perspective. A Descriptive Analysis," *International Journal of Environmental Research and Public Health* 16, no. 14 (2019): 2470, https://doi.org/10.3390/ijerph16142470.

56 Francisco Trujillo Pons, "The 'Digital Disconnect' on the Back of Occupational Health and Safety," *Journal of Leadership, Accountability and Ethics* 20, no. 4 (2023), https://doi.org/10.33423/jlae.v2023i20.6521.

57 Ibid.

58 Ibid.

5. Conclusions

As highlighted in Deloitte,[59] the focus is more proactive, engaging, and preventative initiatives instead of reactive management procedures regarding mental health-related incidents. It also presupposes a shift from the assessment model in OSH to a management system that includes assessment and management of all types of risks, particularly those labelled as "psychosocial" in a digitalized work environment. The interconnections and dependence between the organizational management approach and labor law in OSH must also be considered in this regard.

Theoretical standpoints and reflections regarding the mental health vulnerability concept as a worker's subjective perception of work climate that further establishes their expectations of working conditions embedded in the employment relationship presuppose the recognition and integration of psychological contract elements into traditional employment contracts. Furthermore, reshaping the conventional labor right to rest and leisure to a new reality of digitally driven society could require employing novel mechanisms such as the right to disconnect introduced in some EU countries. Nevertheless, stronger collaboration between states and social partners is necessary to implement these changes and raise awareness about the emerging psychosocial risks of constant connectivity, work-life imbalance, and AI misuse on the mental health and well-being of workers.

The human/worker-centred approach allows employers to look at workers' mental health from an altered perspective, acknowledging that they need to do more to support their mental health and establish a healthier work culture and organizational practice. As mental health issues continue to gain prominence, irrespective of their size and operations, employers can no longer be agnostic to the idea of mental well-being at the (digital) workplaces. They must invest in solving critical challenges, such as investments and raising capabilities, to create a work environment where workers feel safe about their mental health and enjoy a healthy and supportive workspace. Employers should implement a comprehensive, integrated

[59] Deloitte, "Mental Health and Well-Being in the Workplace," 2022, accessed February 18, 2024, https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-mental-health-2022-report-noexp.pdf.

strategy that helps workers stay healthy at work, tackles the root causes of work-related mental health problems, and supports those experiencing mental health symptoms.

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Biomedical Research on Vulnerable Subjects in Bosnia and Herzegovina

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Abstract: Medical research involving human subjects can enhance the well-being of individual patients and provide enormous social benefits. It enables the acquisition of new scientific knowledge and the development of novel therapeutic and diagnostic procedures but also raises significant ethical and legal issues. This kind of medical research is controversial and implies a clash of values that are not always easy to balance. Particularly contentious is research on subjects who are incapable of giving consent or are in a position of subordination and more susceptible to manipulation and mistreatment. Such subjects are considered vulnerable and under special protection. The paper deals with the legal framework of medical research on vulnerable subjects in Bosnia and Herzegovina (its entities: the Republic of Srpska and the Federation of Bosnia and Herzegovina). In the first part of the paper, the notion and basic forms of medical research will be explored, as well as the concept of vulnerability. Reference will be made to relevant international documents defining the standards of medical research on vulnerable subjects. The paper will also provide a comparative overview of provisions governing vulnerable subjects research adopted in different national legislations. In the second part of the paper, the legal framework of medical research on vulnerable subjects in Bosnia and Herzegovina will be analyzed, and suggestions for possible changes will be made.

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1. Introduction: On Relevance and Controversial Nature of Biomedical Research on Human Subjects

The term biomedical research refers to "all types of clinical investigations that have as their ultimate aim the pursuit of clinical knowledge, including those that have a partial therapeutic intent and those that do not."[1] Medical research differs from medical practice in several important ways. Medical practice typically follows established clinical guidelines and protocols based on evidence from prior research and clinical experience. It includes standard treatments that doctors of the same speciality commonly apply. If a new procedure (or medication) is used instead, which has not been previously recognized or applied by many physicians, it represents medical research.[2] Knoppers and Sprumont identify three main differences between medical practice and research. First, while the primary goal of medical practice is to enhance the health and/or well-being of an individual patient, the researcher's goals include those of the medical research itself (the researcher does not act exclusively in the interest of a research subject). Second, the doctor-patient relationship is highly personal, and all physician's activities should be based exclusively on the specific needs of the patient. On the other hand, a researcher must strictly follow the procedures stipulated in the research protocol. Third, research should be based, in principle, on a written protocol defining its purpose, goals, and means, which is "necessary not only to guarantee the quality and reliability of the research results but also to protect the human subjects against unnecessary and unpredicted risks and burdens."[3]

Two basic types of medical research are therapeutic and non-therapeutic. Therapeutic research can be broadly defined as "research that offers some therapeutic benefit to the person participating in the study."[4] Participants in this kind of research "are patients expecting to be treated for their illness as well as to help the researcher gain knowledge which

1 Philip Bielby, *Competence and Vulnerability in Biomedical Research* (Springer, 2008), 50.
2 Jakov Radisic, *Medicinsko pravo* (*Medical Law*) (Beograd: Nomos, 2008), 255.
3 Bartha Maria Knoppers and Dominique Sprumont, "Human Subjects Research, Ethics, and International Codes on Genetic Research," in *Encyclopedia of Ethical, Legal and Policy Issues in Biotechnology*, eds. Thomas H. Murray and Maxwell J. Mehlman (New York: John Wiley and Sons, 2000), 2: 568.
4 Leanne Bell, *Medical Law and Ethics* (Harlow: Pearson Education, 2012), 239.

can be generalized."[5] On the other hand, non-therapeutic research encompasses studies that do not directly aim to benefit individual subjects. Participants in non-therapeutic research are not expected to gain any therapeutic benefits from their involvement. Its primary objective is to generate knowledge, advance scientific understanding, or develop theories. Some authors claim that since research and therapy are fundamentally different, speaking of "therapeutic research" is contradictory, and the term should be abandoned.[6] The term therapeutic research is criticized as ambiguous because it implies some therapeutic benefits for participants, even though these benefits are only hypothetical. It also creates confusion about the exact role of physicians involved in the research process (who, in the context of research, act primarily as investigators, not healers).[7] Bell also complains that the term "non-therapeutic" research is misleading as it suggests that this type of research is somehow of less value; while it may have considerable benefits for persons other than those participating in the study, perhaps sometime after the research is carried out.[8] Levine, who opposes the aforementioned distinction, points out that "[t]he class of activities covered by the term 'therapeutic research' is also problematic because all clinical trials of therapeutic agents include some components that may be therapeutic (...) and others that are clearly nontherapeutic."[9] Those who rely on the distinction between therapeutic and non-therapeutic research will usually categorize research protocols with one or more therapeutic components as therapeutic research. As a consequence, all components of such protocols will be evaluated/justified according to relatively permissive standards for therapeutic research (Levine calls this phenomenon the "fallacy of the package deal").[10] Although the distinction between therapeutic and non-therapeutic research has been abolished in some national

5 Claire Foster, *The Ethics of Medical Research on Humans* (Cambridge: Cambridge University Press, 2004), 38.

6 Knoppers and Sprumont, "Human Subjects Research, Ethics, and International Codes on Genetic Research," 568.

7 Ibid.

8 Bell, *Medical Law and Ethics*, 239.

9 Robert J. Levine, "The Need to Revise the Declaration of Helsinki," *The New England Journal of Medicine* 341, no. 7 (1999): 531.

10 Ibid.

legislations (in the United States (US) and Canada as far back as the 1970s)[11] and relevant international documents (the Declaration of Helsinki),[12] it still significantly impacts the regulatory framework of medical research in the majority of European countries.[13]

Medical research on human subjects is of utmost importance. It can enhance the well-being of individual patients and provide enormous social benefits. It is indispensable for advancing medical knowledge, improving healthcare outcomes, and addressing public health issues. Medical progress depends on medical research, which, ultimately, requires the involvement of human subjects.[14] As certain authors point out: "One thing is undisputed in the very controversial field of clinical trials: medical research is absolutely necessary."[15]

However, it also raises numerous ethical and legal dilemmas. Medical research involving human subjects is necessarily controversial and implies a confrontation of values that are not always easy to balance. As Jay Katz notes: "When science takes man as its subjects, tensions arise between two values basic to Western society: freedom of scientific inquiry and protection of individual inviolability."[16] Medical research on human subjects touches upon their right to life and physical integrity. Although medical treatments also put patients at risk, "the risks involved in the biomedical research tend to be graver, since the methods used have not yet been proved, and their effects may not all be known."[17] This kind of medical research is also problematic from the perspective of protecting the value of human dignity. A certain degree of instrumentalization, necessarily present in medical

11 Ibid.

12 The distinction between "therapeutic" and "non-therapeutic" research was abolished in the 2000 revision of the Declaration (Karmela Krleza-Jeric and Trudo Lemmens, "7th Revision of the Declaration of Helsinki: Good News for the Transparency of Clinical Trials," *Croatian Medical Journal* 50, no. 2 (2009): 106).

13 Radisic, *Medicinsko pravo* (*Medical Law*), 256.

14 Henning Rosenau, "Legal Prerequisites for Clinical Trials under the Revised Declaration of Helsinki and the European Convention on Human Rights and Biomedicine," *European Journal of Health Law* 7, no. 2 (2000): 105.

15 Ibid.

16 Jay Katz, *Experimentation with Human Beings* (New York: Russel Sage Foundation, 1972), 1, quoted in Knoppers and Sprumont, "Human Subjects Research, Ethics, and International Codes on Genetic Research," 567.

17 Rosenau, "Legal Prerequisites for Clinical Trials," 106.

trials, makes research on human subjects morally problematic (because it can potentially cause the violation of the second formulation of Kant's categorical imperative: never treat a person merely as a means to someone else's end but always also as an end in themselves). The protection of the dignity of an individual requires that participation in medical research be based on the subject's voluntary informed consent (as the principle deeply entrenched in the concept of "dignity as empowerment").[18] However, the problem of informed consent, or respect for individual autonomy/dignity, is not the only issue relevant from the perspective of human dignity protection. The subject's consent may not always be sufficient to legitimize medical research. The other Janus face of human dignity ("dignity as constraint") also comes to the fore in the context of human subject research. Controversial issues in which the constraining dimension of human dignity plays a role, as some authors note, are the experimentation on human embryos or the mixing of human and non-human DNA[19] (but also other research that is potentially problematic from the perspective of respect for public morality). The importance of human dignity protection, in both its empowering and constraining sense, has been explicitly highlighted in some national research ethics guidelines. For example, Canada's *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* from 1998 provided for the obligation to respect inherent dignity as a moral absolute (one should never treat others merely as a means to an end) but also stressed the fact that all of humanity can be impoverished by research that shows disrespect for human dignity.[20]

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18 Beyleveld and Brownsword differentiate between "dignity as empowerment" and "dignity as constraint". According to the authors, the conception of "dignity as empowerment" implies that "the function of human dignity is to reinforce claims to self-determination rather than to limit free choice" (Deryck Beyleveld and Roger Brownsword, *Human Dignity in Bioethics and Biolaw* (Oxford: Oxford University Press, 2001), 28). On the other hand, the conception of "dignity as constraint" acts as "a constraint on free choice" (Ibid., 11).

19 While many researchers and consumers argue that respect for their inherent dignity justifies granting a free hand in research on human subjects, others oppose and call for greater regulation on the grounds of protecting dignity (Lawrence Burns, "What is the Scope for the Interpretation of Dignity in Research Involving Human Subjects?," *Medicine, Health Care and Philosophy* 11, no. 2 (2008): 193–4).

20 Ibid., 191.

Thus, the remark made by Jean Bernard, the first chairman of the French National Ethics Committee, about human experimentation as "morally necessary and necessarily immoral" is not without merit.[21] Particularly controversial is research performed on subjects who are unable to give consent or are in a position of subordination and more susceptible to pressure and manipulation. Such subjects are considered vulnerable and under special protection (which will be explored in more detail within this paper).

2. The Concept of Vulnerability in Medical Research on Human Subjects

Medical research on vulnerable subjects refers to studies that involve individuals or groups who are "presumed to be more likely than others to be misled, mistreated, or otherwise taken advantage of as participants in research."[22] A vulnerability status generates an obligation for legislators, researchers, and ethics committees to provide special protection for this category of subjects.

The term "vulnerable" originates from the Latin verb *vulnerare*: to wound. This original meaning of the term is still present today. The *Oxford English Dictionary*, for example, lists "susceptible of receiving wounds or physical injury" as a primary definition of "vulnerability".[23] However, the meaning of this term transcends mere susceptibility to physical harm. It also includes "a predisposition to certain types of psychological and/or developmental harm that an individual has an interest in avoiding."[24] Bielby differentiates between two meanings of vulnerability: (1) baseline vulnerability (which expresses the condition of all human beings as able to be hurt, wounded, or killed), and (2) heightened vulnerability (which relates to those individuals who are more susceptible than usual to being hurt or

21 Quoted in Knoppers and Sprumont, "Human Subjects Research, Ethics, and International Codes on Genetic Research," 567.

22 Carol Levine at al., "The Limitations of 'Vulnerability' as a Protection for Human Research Participants," *The American Journal of Bioethics* 4, no. 3 (2004): 44.

23 *Oxford English Dictionary*, 2nd ed., quoted in Bielby, *Competence and Vulnerability in Biomedical Research*, 52.

24 Bielby, *Competence and Vulnerability in Biomedical Research*, 52.

injured).[25] A heightened state of vulnerability can be caused by various cognitive and circumstantial factors, such as immaturity, old age, physical illness or injury, mental illness or impairment, socio-economic disadvantages, physical or psychological trauma, institutionalization, membership of a minority group that experiences prejudice or mistreatment, etc.[26] Depending on the factors that cause the individuals' heightened vulnerability, Bielby distinguishes between cognitive and circumstantial vulnerability (although, as the author points out, these two forms of increased vulnerability may overlap).[27] Both of these forms of heightened vulnerability are relevant in the context of human subject research.

The concept of vulnerability has long played a central role in discussions on research ethics.[28] One of the reasons for the frequent use of this term was a significant number of ethically problematic research recorded in medical practice.[29] However, the concept remains elusive despite the frequency with which the term vulnerability is used. Certain assistance in determining the meaning of this term can be provided by international documents and national regulatory acts governing research on human subjects. For example, the US Common Rule, the centrepiece of human research

25 Ibid., 53.

26 Ibid., 54. As stated in the CIOMS's "International Ethical Guidelines for Health-related Research Involving Humans", persons may be vulnerable when they have relative or absolute impairments in decisional capacity, education, resources, strength, or other attributes needed to protect their own interests. However, persons can also be vulnerable because some feature of the circumstances (temporary or permanent) in which they live makes it less likely that others will be vigilant about, or sensitive to, their interests (Commentary on Guideline 15) (Council for International Organizations of Medical Sciences (CIOMS), "International Ethical Guidelines for Health-related Research Involving Humans" (2016)).

27 Ibid. Individuals with mental disorders or intellectual disabilities and children are primarily cognitively vulnerable, while the economically disadvantaged, prisoners, the uneducated and persecuted are primarily circumstantially vulnerable (since the circumstances that make them vulnerable are contingent on social, political, and legal arrangements).

28 Carl H. Coleman, "Vulnerability as a Regulatory Category in Human Subjects Research," *The Journal of Law, Medicine & Ethics* 37, no. 1 (2009): 12.

29 Levine et al., "The limitations of 'vulnerability,'" 45; Michael G. White, "Why Human Subjects Research Protection is Important," *Ochsner Journal* 20, no. 1 (2020); Todd W. Rice, "The Historical, Ethical, and Legal Background of Human-Subjects Research," *Respiratory Care* 53, no. 10 (2008): 1327.

subject protection in this country, uses the term "vulnerable" three times.[30] Although the Common Rule does not define vulnerability,

> each time the word is used, it is accompanied by the phrase 'such as children, prisoners, pregnant women, or handicapped or mentally disabled persons' and, in two of the three sections, 'economically or educationally disadvantaged persons'.[31]

It is evident that the document refers to both forms of heightened vulnerability (according to Bielby's classification mentioned above). Some other relevant provisions related to vulnerability in research will be discussed below.

3. International and European Standards on Medical Research Involving Human Subjects

The Nuremberg Code[32] of 1947 provided the first international rules for scientific experiments on human participants. Introduced as a response to horrifying Nazi "medical" experiments, the Code "firmly established the principle of patient self-determination."[33] The opening line of the first of its ten principles states: "The voluntary consent of the human subject is absolutely essential." The Code's first principle also explicitly excludes vulnerable groups from medical experimentation. Medical experiments on persons who do not have legal capacity or are not able "to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion" are prohibited. The prohibition of medical experimentation on vulnerable subjects is also prescribed by the UN's International Covenant on Civil and Political Rights[34] (ICCPR) of 1966. Article 7 of the ICCPR excludes the possibility of

30 Coleman, "Vulnerability as a Regulatory Category in Human Subjects Research," 12.

31 Ibid.

32 Nuremberg Code of 1947, *British Medical Journal* 313, no. 7070 (1996): 1448.

33 Jose Miola, *Medical Ethics and Medical Law. A Symbiotic Relationship* (Oxford: Hart Publishing, 2007), 34.

34 The International Covenant on Civil and Political Rights, United Nations (1966), accessed February 28, 2024, https://www.ohchr.org/en/instruments-mechanisms/instruments/international-covenant-civil-and-political-rights.

medical experimentation without a subject's free consent.[35] The exclusion of vulnerable persons or groups from medical research due to rigid voluntary consent requirements has been criticized since it deprives some individuals of the right to participate in clinical trials.[36] The General Medical Council's 2002 guidance "Research: The Role and Responsibilities of Doctors" suggests that excluding vulnerable research subjects could be considered a form of discrimination.[37]

The Declaration of Helsinki (DoH),[38] adopted by the World Medical Association (WMA) in 1964 (amended seven times since, the latest revision made in 2013), is described in the literature as "the first attempt to formulate a universal code for the practice of medical research"[39] and "the cornerstone document of human research ethics."[40] The Declaration describes vulnerable groups and individuals as those who "may have an increased likelihood of being wronged or of incurring additional harm" (Article 19). Unlike the Nuremberg Code and the ICCPR, the Declaration allows medical research on vulnerable subjects under certain conditions. According to Article 20 of the Declaration, medical research with vulnerable groups is only justified if it is responsive to the group's health needs or priorities and the research cannot be carried out in a non-vulnerable group. This article also requires that a vulnerable group should stand to benefit from knowledge, practices, or interventions that result from research. If a potential research subject is incapable of giving informed consent, the physician must seek informed consent from their legally authorized representative

35 Ulf Schmidt, "From Nuremberg to Helsinki: Historicizing the Codification of the Post-War Research Ethics," in *Ethical Innovation for Global Health: Pandemic, Democracy and Ethics in Research*, eds. Chieko Kurihara, Dirceu Greco, and Ames Dhai (Springer, 2023), 154.

36 Mary C. Ruof, "Vulnerability, Vulnerable Populations and Policy," *Kennedy Institute of Ethics Journal* 14, no. 4 (2004): 411.

37 General Medical Council, "Research: The Role and Responsibilities of Doctors," 2002, para. 43, quoted in Bielby, *Competence and Vulnerability in Biomedical Research*, 51.

38 World Medical Association, The Declaration of Helsinki, 1964 (the 2013 version), accessed February 27, 2024, https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/.

39 Stuart J. Horner, "Retreat from Nuremberg: Can We Prevent Unethical Medical Research?," *Public Health* 113, no. 5 (1999): 205.

40 Badri Shrestha and Louese Dunn, "The Declaration of Helsinki on Medical Research involving Human Subjects: A Review of Seventh Revision," *Journal of Nepal Health Research Council* 17, no. 4 (2019): 548.

(Article 28). Furthermore, the Declaration requires that minors or legally incompetent subjects provide their consent, indicating a strong commitment to respecting a research subject's person (i.e. their dignity). According to Article 29 of the DoH, when a potential research subject incapable of giving informed consent can give assent regarding their participation in research, the physician must seek that assent in addition to the consent of the legally authorized representative (the potential subject's dissent should also be respected) (Article 29).

In Europe, medical research on human subjects is regulated by the European Union (EU) law and the documents adopted by the Council of Europe (CoE). In the EU, the oversight of research with human participants is divided between EU-level law and the laws of the Member States.[41] Clinical medical research is subject to the Clinical Trials Regulation 536/2014[42] (which repealed the Clinical Trials Directive 2001/20/EC on 31 January 2022). Article 10 of the Regulation provides for specific considerations for vulnerable persons. Article 10(1) stipulates that:

> Where the subjects are minors, special consideration shall be given to the assessment of the application for authorization of a clinical trial on the basis of paediatric expertise or after taking advice on clinical, ethical and psychosocial problems in the field of paediatrics.

The Regulation also considers incapacitated subjects and pregnant or breastfeeding women as a vulnerable population that requires special considerations (Article 10(2) and (3)). Research in the EU is also subject to a variety of human rights principles (some of which are derived from the EU's Charter of Fundamental Rights and are enforced by the European Court of Justice, but since the EU Member States are also members of the CoE, medical research in EU countries is subject to the jurisdiction of the European Court of Human Rights).[43]

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41 Carl H. Coleman, "Introduction to Research with Human Participants," in *The Oxford Handbook of Comparative Health Law*, eds. David Orentlicher and Tamara K. Hervey (New York: Oxford University Press, 2022), 609.

42 EU Clinical Trial Regulation no. 536/2014, accessed February 18, 2024, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014R0536.

43 Coleman, "Introduction to Research with Human Participants," 609.

In 1997, the Parliamentary Assembly of the Council of Europe adopted 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, also known as the Oviedo Convention),[44] considered as "one of the most important bioethics texts from the point of view of international policy and law."[45] Chapter V of the Convention (Articles 15–18) lays down general rules for biomedical research on human subjects. Article 15 of the Convention stipulates that research in the field of biology and medicine may be carried out freely but always subject to the provisions of the Convention and other legal provisions ensuring the protection of human beings. Article 16 determines the conditions for research on human subjects: no alternative of comparable effectiveness exists (e.g. animal research); the risks for the research subjects should not be disproportionate to the potential benefits of the research; the research project should be approved by the competent body after independent examination of its scientific merit; research subjects should give their free, explicit, and informed consent, in accordance with Article 5 of the Convention, which may be freely withdrawn at any time. Article 17 regulates research on persons not able to consent. This kind of research may only be undertaken if its results have the potential to produce real and direct benefits to a subject of research, and the research of comparable effectiveness cannot be carried out on persons capable of giving consent (the Convention also requires that the necessary authorization of a legally authorized representative be given specifically and in the written form). Exceptionally, research without direct therapeutic benefit may be authorized if it "entails only minimal risk and minimal burden for the individual concerned" (Article 17(2)).

In 2005, the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research[46] (Additional Protocol)

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44 The Parliamentary Assembly of the CoE, The Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, 1997, accessed February 26, 2024, https://rm.coe.int/168007cf98.

45 Gilbert Hottois, "A Philosophical and Critical Analysis of the European Convention of Bioethics," *Journal of Medicine and Philosophy* 25, no. 2 (2000): 133.

46 The Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Biomedical Research (ETS no. 168), CoE, 2005, accessed February 24, 2024, https://rm.coe.int/168007f2ca.

was adopted. According to Article 3 of the Additional Protocol: "The interests and welfare of the human being participating in research shall prevail over the sole interest of society or science." Article 14(1) stipulates that no research on a person may be carried out without their "informed, free, express, specific and documented consent". Article 15 of the Additional Protocol regulates the protection of persons not able to consent to research. It stipulates that research on a person without the capacity to consent may be carried out only if the research results have the potential to produce real and direct benefits to their health, and research of comparable effectiveness cannot be performed on individuals capable of giving consent. The Additional Protocol requires that the necessary authorization be given specifically and in written form by the legal representative or an authority, person, or body provided for by the law. According to Article 15(1)(iv), an adult subject who is not able to consent should, as far as possible, take part in the authorization procedure. The Protocol also requires that the opinion of a minor should be taken into account "as an increasingly determining factor in proportion to age and degree of maturity" (Article 15(1)(iv)).

The Explanatory Report to the Additional Protocol, adopted by the Council of Europe in 2005, "contains the most detailed taxonomy of vulnerability in a contemporary ethical code."[47] The Explanatory Report provides an extensive classification of vulnerable groups according to cognitive, situational, institutional, deferential, medical, economic, and social factors (as pointed out in the Report, membership of these groups can overlap).[48]

Bosnia and Herzegovina ratified the Oviedo Convention and the Additional Protocol in 2007 (they came into force on 1 September 2007).

4. Comparative Overview of the Human Subject Research Regulation

For a long time, most countries have not had any ethical regulations for medical research. However, in many Western countries, the ethical framework regulating medical research on human subjects has been consolidated

47 Bielby, *Competence and Vulnerability in Biomedical Research*, 60.

48 The Explanatory Report to the Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Biomedical Research, Council of Europe, 2005, accessed February 21, 2024, https://rm.coe.int/16800d3810.

since the 1980s.[49] The Federal Policy for the Protection of Human Subjects (the "Common Rule") came into force in the US in 1981. France adopted special legislation in 1988, establishing forty-eight Committees for the Protection of Persons throughout the country. Although the first research committees in Germany were established in the 1970s, committee approval of clinical trials was not mandatory until 1994.[50]

The current French Law no. 2012–300 of 5 March 2012 on research involving human subjects, known as "Jardé law", came into force in 2016. It stipulates that for adults who are protected or incapable of consenting (e.g. coma, senile dementia, psychiatric reasons, or enfeebled patients), authorization is required from the tutor or the curator for protected adults and minors (Article L.1122–2 II, §3), or from the designated person of trust, a family member by default, or a person with strong and reliable ties to the patient (as a last resort) (Article L.1122–2 PHC). When it comes to medical research on minors, in principle, both parents must consent to any interventional research on their child, whether it entails minimal risk or not (research categories 1 and 2) (Article L.1122–2 II PHC). Exceptionally, the present parent can give consent if the research involves minimal risks and two conditions are met: (1) the minor must not qualify as a healthy volunteer, and (2) the collection of the other parent's consent is incompatible in terms of time frame with the methodological requirements of the study with regards to its objectives (Article L.1122–2 II PHC). The Law differentiates between three categories of research involving human subjects: Category 1: interventional research implying an intervention that is not risk-free for the research subjects and is not justified by their usual care; Category 2: interventional research with minimal risks and constraints; Category 3: non-interventional research implying acts and procedures that are risk-free. The Law also stipulates that people deprived of their freedom by legal or administrative decisions or people benefiting from psychiatric care unable to express their consent can only participate in interventional research (categories 1 and 2) if the direct expected advantage for these subjects justifies the foreseeable risks or there is an expected advantage for

[49] David F. Kelly, Gerald Magill and Henk ten Have, *Contemporary Catholic Health Care Ethics* (Georgetown University Press, 2013), 263.

[50] Ibid.

people in the same situation, while the research cannot be conducted on other types of subjects (the Law, therefore, also regulates certain forms of circumstantial vulnerability).[51]

In Germany, participation in medical research of subjects incapable of giving consent requires the approval of their legal representatives. A potential subject's assent for participation in research is also needed, provided that the person is capable of understanding the nature, significance, and implications of clinical investigation and is able to form a rational opinion based on these facts. In clinical studies with minors, consent should be given by the legal representative. If the minor is able to understand the nature, significance, and implications of the clinical research, their assent is also required.[52] In Poland, a legally incapacitated person is required to provide written assent if they are able to consciously express their opinion. In cases of clinical research on minors, those over the age of 16 need to give their written assent (minors under 16 can also give their assent if they are able to express their own opinion).[53] On the other hand, Russian legislation does not provide for the inclusion of incapacitated persons or minors in the process of obtaining informed consent.[54] The Patients' Rights Act of Montenegro[55] also does not contain an assent requirement. It stipulates that scientific examination and research can be undertaken exceptionally on a minor or a patient deprived of legal capacity, but only for their immediate benefit and with the written consent of their legal representative, who has been previously informed about the purpose, goal, course of the procedure, expected results, potential risks, as well as possible side effects of testing and research (Article 23).

51 Elisabet Toulouse et al., "French Legal Approach to Clinical Research," *Anaesthesia Critical Care & Pain Medicine* 37, no. 6 (2018).

52 Marcin Orzechowski et al., "Normative framework of informed consent in clinical research in Germany, Poland, and Russia," *BMC Medical Ethics* 22, no. 1 (2021), accessed February 27, 2024, https://bmcmedethics.biomedcentral.com/articles/10.1186/s12910-021-00622-6.

53 Ibid.

54 Ibid.

55 The Patients' Rights Act of Montenegro, Official Gazette of Montenegro, no. 40/2010 and 40/2011.

5. Legal Framework of Research on Vulnerable Subjects in Bosnia and Herzegovina

Bosnia and Herzegovina is a complex state community which consists of two entities: the Republic of Srpska (RS) and the Federation of Bosnia and Herzegovina (FBiH) (the Brcko District (BD) is a third territorial unit; BD is a small subnational unit that enjoys broad legislative autonomy). The distribution of competences between BiH and the entities is determined by the Constitution of BiH in such a way that BiH is assigned the competences for regulating issues that are expressly stated in the Constitution of BiH, while all other issues are solely the responsibility of the entities.[56] The BiH entities and the BD are responsible for regulating health protection in BiH.

In the RS, under Article 14(3) of the RS Constitution,[57] no person can be subject to medical or other scientific experiments without their consent. In accordance with the aforementioned constitutional provision, the RS Health Protection Law[58] (RS HPL) stipulates that medical research on an adult and legally competent patient can be conducted only with their informed consent given in written form. The RS HLP also regulates the participation in clinical research of persons incapable of giving consent. Under Article 52(2) of the RS HPL, clinical research on a minor or a person deprived of legal capacity may only be conducted in exceptional cases if there is an indication for medical treatment and when written consent is given by the minor's parent or guardian, or the legal representative of the person deprived of legal capacity.

The Code of Medical Ethics and Deontology of the RS Medical Doctor's Chamber[59] also regulates physicians' responsibilities related to medical research. Article VI(3) of the Code states that physicians must adhere to the Declaration of Helsinki and its revisions when conducting scientific research. If a potential subject is minor or not capable of giving consent due

[56] Article III(1) and Article III(3) of the Constitution of Bosnia and Herzegovina, accessed February 19, 2024, https://www.ustavnisud.ba/uploads/documents/constitution-of-bih_1625734692.pdf.

[57] The Constitution of the Republic of Srpska, accessed February 17, 2024, https://www.narodnaskupstinars.net/sites/default/files/upload/dokumenti/ustav/eng/USTAV-RS_English.pdf.

[58] The Health Protection Law, Official Gazette of the Republic of Srpska, no. 57/2022.

[59] The Code of Medical Ethics and Deontology of the RS Medical Doctor's Chamber, accessed February 18, 2024, https://komoradoktorars.org/index.php/2018-11-26-17-31-48/s-l/d-s-dicins-i-i-d-n-l-gi.

to lack of legal capacity or their state of consciousness, consent is requested from their legal representative (Article VI(6)). The Code also stipulates that the physician should pay particular attention to the situations where the subject's ability to refuse consent is significantly compromised due to their reliance on the physician (Article VI(8)). The physician is obliged to present the research plan for assessment in terms of scientific and educational justification and ethical acceptability to the authorized institution (Article VI(3)).

In the FBiH, a federally organized entity, health protection regulation is one of the shared responsibilities of the Federation and its cantons[60] (the FBiH consists of ten federal units called cantons). According to Article 38(1) of the FBiH Law on Rights, Obligations and Responsibilities of Patients,[61] informed consent is required for medical and scientific research or clinical testing of drugs and medical devices on a patient, as well as including them in educational activities. In the case of minors or legally incompetent patients, consent is obtained from their parents, guardians or legal representatives while also taking into account the minor or legally incompetent patient's opinion (Article 38(3)). Under Article 38(5) of the Law, the legal provisions on the protection of persons with mental disorders are applied accordingly to the rights of patients with mental disorders who participate in research. According to Article 16 of the FBiH Law on Protection of Persons with Mental Disorders,[62] medical research on persons with mental disorders can only be undertaken if a person participating in the study has given written consent, the research is related to the treatment of a mental disorder experienced by that person, and the presumed risk of the research to the person with a mental disorder is not disproportionate to its benefit. If the person with mental disorders is unable to consent, the consent of the subject's legal representative is required.

60 Article 2 of the Constitution of the Federation of Bosnia and Herzegovina, Official Gazette of the Federation of Bosnia and Herzegovina, no. 1/94, 13/97, 16/02, 22/02, 52/02, 60/02, 18/03, 63/03, 9/04, 20/04, 33/04, 71/05, 72/05, 88/08.

61 The Law on Rights, Obligations and Responsibilities of Patients, Official Gazette of the Federation of Bosnia and Herzegovina, no. 40/2010.

62 The Law on Protection of Persons with Mental Disorders, Official Gazette of the Federation of Bosnia and Herzegovina, no. 37/2001, 40/2002, 52/2011, and 14/2013.

In 2009, the Agency for Medicinal Products and Medical Devices of BiH (ALMBiH) was established as "an authority responsible in the area of medicinal products and medical devices which are manufactured and used in medical practices in Bosnia and Herzegovina" (Article 3(1) of the BiH Medicinal Products and Medical Devices Act (MPMDA)).[63] The ALMBiH is responsible for registering and approving clinical trials of medicinal products and monitoring adverse effects occurring during clinical trials (Article 7(1)(d)). After local ethics committees established within the entity-level university clinical centres (or within other health institutions authorized to conduct clinical trials) approve a clinical trial application, it is submitted to ALMBiH for approval. The ALMBiH's committee for clinical trials, which consists of seven members, assesses documentation enclosed in the application for obtaining permission for clinical trials of medicinal products and the application for registering the clinical trial or an amendment or annex to the already registered and approved clinical trial protocol (Article 24 of the MPMDA). According to the Ordinance on Clinical Trials on Medicinal Products and Medical Devices,[64] if the candidate is incapable of giving personal consent for the participation in a clinical trial on the medicinal product, if they are not conscious or not capable of reasoning, the consent may be given by parents, guardians, legal representatives, spouse, and if the researcher believes that the participation may be useful for the well-being and interests of the research subject (Article 14(j)). If necessary, and under special precautions, a clinical trial may be conducted on minors suffering from a disease or from a condition for which the tested medicinal product is intended. Clinical trial that includes a minor may be conducted if: (1) a parent or legal guardian has given written consent (written consent should represent the presumed will of a minor and may be withdrawn at any time, without harm to them), (2) a minor has been provided with information that is understandable to them by a person who has experience in working with minors, and (3) written consent has been given without the encouragement to participate in a clinical trial (Article 15 of the Ordinance).

63 The Medicinal Products and Medical Devices Act, Official Gazette of Bosnia and Herzegovina, no. 58/2008.

64 The Ordinance on Clinical Trials on Medicinal Products and Medical Devices, Official Gazette of Bosnia and Herzegovina, no. 4/2010.

6. Conclusion

Medical research involving human subjects can enhance the well-being of individual patients and provide enormous social benefits. It enables the acquisition of new scientific knowledge and the development of novel therapeutic and diagnostic procedures but also raises significant ethical and legal issues. Particularly controversial is research on subjects who are incapable of consenting to the study or are in a position of subordination and more susceptible to manipulation and mistreatment. Such subjects are considered vulnerable and the object of special protection. Nevertheless, it is necessary to ensure access to medical research for vulnerable individuals and groups in order to enable them to benefit from it. The various forms of research subjects' vulnerability should be considered when regulating medical research.

The analysis of the legal framework of medical research in BiH (BiH entities) showed that it complies with basic international and European standards regarding protecting research subjects, including those who are incapable of consenting. However, some changes to the entity legislation are appropriate. One of the justified legislative changes in the RS would be the introduction of an assent requirement, while participation in the decision-making of research subjects incapable of giving consent should be more precisely regulated in the FBiH legislation.

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Informed Consent in Clinical Studies in the Republic of Srpska

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Abstract: As human medicine is developing at a galloping pace, continuously offering new medical products, diagnostic methods and preventive programmes, there is almost no time gap between their creation and application in medical practice. All these biomedical achievements are primarily intended to improve public health and the patient's quality of life and health. Hence, it is important to define potential risks, side effects, and unwanted outcomes when applying a medical product/treatment before integrating it into healthcare. Unlike any other product/treatment intended for human use, medical products/treatments require prior clinical testing on human subjects (sick or sound). The authors of this paper have restricted their scientific interest to the participant (human subject) of a clinical study as one of the core elements of a clinical investigation, representing at the same time its means and its aim. By analyzing relevant international as well as national legal rules and ethical principles of the Republic of Srpska related to the participation of humans in clinical studies, it will be concluded that the participants' safety and right to self-determination, integrity, and autonomy manifested through their independent right to either consent or refuse to participate in a clinical study supersedes the interests of science or society. However, clinical trial-related

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statistical data obtained from randomly chosen healthcare institutions in the Republic of Srpska will show certain derogations from prescribed ethical policies. Considering this fact, the authors have paid special attention to thematising the ethicality of recruiting participants for a clinical study based on partial or no information related to the purpose, methods, potential risks and side effects of the investigation in the name of the greater good for humanity. Such practice has accentuated the discretionary powers of ethical review committees on the one side and the uncertainty of the right to informed consent on the other.

1. Introduction

Clinical experiments/trials/investigations/studies on human subjects have always been justified as *ultima ratio* when all other methods or means of study could not yield results for the good of society. However, certain legal and ethical standards of medical behavior must be respected when the subject of clinical study is a human being. One of the basic requirements is voluntary informed consent[1] obtained from every participant before any clinical study.

Informed consent is not just the act of signing a confirmation form but rather a complex process of providing the participant with sufficient information about the nature, duration, and purpose of the study; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon health or person of the participant which may be the result of participation in the experiment.[2] All possible risks must be weighed against the expected benefits, and all unnecessary physical and mental suffering must be avoided. These Nuremberg standards for carrying out experiments on human subjects have been extended into general codes of medical ethics.

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1 About legal, ethical and clinical aspects of informed consent in all medical interventions, except clinical studies, see: Snežana Pantović and Dijana Zrnić, "Ethical, Clinical and Legal Aspects of Informed Consent in Montenegro, Republic of Srpska, Serbia and Croatia," *International Scientific Conference: Challenges and Perspectives of the Development of Legal Systems in the XXI Century – Conference Proceedings* 1, no. 3 (2023): 115–33, https://doi.org/10.7251/NSTT12301115P.

2 "The Nuremberg Code of 1947," *British Medical Journal* 313, no. 7070 (1996): 1448.

The Republic of Srpska has formalized and accorded its principles and protocols related to clinical studies to the highest legal and ethical standards accepted worldwide, starting from the Nuremberg Code, the International Covenant on Civil and Political Rights of the United Nations, the Helsinki Declaration, the CIOMS Guidelines of 2002, the WHO Good Clinical Practice Guide of 1995, Guidelines for Good Clinical Practice (GCP) for Pharmaceutical Products of International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use of 1996, the European Council's Convention of the Protection of the Human Beings with regard to the Applicant of Biology and Medicine: Convention on Human Rights and Biomedicine (1997, came into effect in 2009); the European Council's Additional Protocol to the Conventions on Human Rights and Biomedicine, considering Biomedical Research (2009); Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 (came into effect on 2004) on the approximation of the laws, regulations and administrative provisions of the Member States of Clinical Trials on medicinal products for human use; and all other rules and regulations related to clinical studies.

This study will primarily focus on the nature of Informed Consent in Clinical Studies in the Republic of Srpska and the extent of information provided to participants about the clinical study before they consent to any kind of clinical testing. In addition, the connection between risks and direct benefits to the participants will also be explored. In the process of analyzing legal and ethical solutions and recommendations, the authors intend to highlight any dilemmas or unpopular trends in clinical practice related to informed consent, such as engaging sick patients to avoid compensation and/or insurance obligations, (un)ethical recruiting of healthy individuals, breaching the minimal risk principle, etc.

It will be concluded that the Republic of Srpska healthcare regulatory system and ethical policies insist on fully informed consent before any clinical study, stressing the predominance of the protection and safety of human life and health over any scientifically and/or socially beneficial research results. Urgent situations and/or psychological stability of the participant, however, open the door to modifications of informed consent in the sense of allowing temporary retention of information from the participant in the recruiting process. The clinical practice has shown that, without a strict

review mechanism, these extraordinary situations will provide ample room for manipulations and unethical conduct of the investigators whose primary interest is not necessarily the safety and well-being of the participant.

2. The Concept of Informed Consent in a Clinical Study

2.1. Clinical Study

What is a clinical study? It is an investigation involving human subjects aiming at answering a specific medical question. A careful and quality clinical study is the safest way to discover new types of treatment and health improvement methods in humans. In oncology, for example, an interventional study analyzes whether a new/experimental treatment or a standard treatment applied in a new way is safer, more efficient and better under controlled conditions than the existing treatment. In other words, any investigation involving human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product, and/or to identify any adverse reactions to an investigational product, and/or to study absorption, distribution, metabolism, and excretion of an investigational product with the object of ascertaining its safety and/or efficacy, can be termed a clinical study.[3] Most medications and other forms of treatment currently in use result from clinical studies confirming their efficacy.

Clinical studies are carried out by a study team comprised of a physician, medical nurse, and other healthcare personnel. Every clinical study is based on a detailed study plan (protocol) to ensure the safety of participants and the relevance of study results. The protocol, among other things, anticipates eligibility criteria for the participants (inclusion and exclusion criteria), diagnostic testing plan, medicinal application procedure, and study duration.

Well-designed clinical studies are highly beneficial for patients, who can thus actively contribute to their treatment by gaining access to the latest modes of treatment before they become widely applicable. They represent other patients diagnosed with a similar disease and voluntarily contribute

[3] Section 1.12 of Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice ICH E6 (R2) (2016).

to advancing medical science. Usually, the participants are divided into experimental and control groups. The experimental group receives a new medical product/treatment, while the control group receives a standard treatment or placebo. The control group helps compare the research results with the current standard.

Clinical studies are carried out in phases. First, there is a preclinical phase, which implies *in vitro* and *in vivo* testing on animals. Then, a clinical study follows, which can be divided into four phases (I–IV). The first phase implies an investigation involving a small cluster of healthy individuals (usually 20–80). If the product/treatment is effective, the number of participants will increase in every following phase. The recruitment procedure is gradual to ensure the safety of the participants.

Clinical studies can be funded by various organisations or individuals, such as physicians, healthcare institutions, consortiums, voluntary groups, pharmaceutical companies, or state agencies. The financial component plays a crucial role in performing clinical studies. Unfortunately, promising medical treatments/products are stopped in the preclinical phase without sufficient sponsorship. More often than not, clinical studies are dictated by the financial interests of stakeholders, such as pharmaceutical companies, rather than by altruism. The Gajić family case stands well in support of this argument. This family from Banja Luka (Republic of Srpska), whose two daughters suffer from Lafora disease, is the biggest donor to Lafora disease research worldwide. However, since the number of people (primarily children) suffering from this disease is insignificant, few pharmaceutical companies are interested in funding a clinical study of a new therapeutic strategy developed at the Toronto University Laboratory.[4] Hence, the future of Lafora patients very much depends on the benevolence of willing private donors and the fundraising campaigns of their families.

[4] On Lafora disease and the Gajić family, see a documentary, *The Faces of Lafora* (2017), directed by Denis Bojić, https://www.youtube.com/watch?v=EP7OIQBN1jY; on a new therapeutic strategy for Lafora disease, see: Rashmi Parihar and Subramaniam Ganesh, "Lafora Progressive Myoclonus Epilepsy: Disease Mechanism and Therapeutic Attempts," *Journal of Biosciences* 49, no. 22 (2024): 1–15; Felix Nitschke et al., "Lafora Disease – From Pathogenesis to Treatment Strategies," *Nature Reviews Neurology* 14 (2018): 606–17, https://doi.org/10.1038/s41582-018-0057-0.

Next to qualified investigators, eligible participants, and willing sponsors, clinical studies depend on material and technical resources, which are relatively scarce in low and middle-income countries/regions, such as the Republic of Srpska. In resource-limited populations, numerous barriers exist to prevent clinical study design and implementation. Commonly cited examples are lack of infrastructure, heterogeneity of resource availability among countries, unfamiliarity with clinical study regulations, cultural/ethical issues, and other legal and administrative constraints around data-sharing.[5] Few healthcare facilities in the Republic of Srpska meet the set-up requirements for performing clinical research on humans due to unreasonably strict and complex government regulatory systems, unnecessary delays in ethical approval procedures, and meagre government funding.

2.2. Informed Consent in a Clinical Study

Clinical studies performed on human subjects carry greater risk to the life and health of the participants, requiring stricter subject-oriented regulatory policies. Thus, voluntary informed consent has become the central institute of international and national legal and ethical guidelines that regulate clinical studies. The main difference between a clinical study and a medical treatment subject-wise is that a study participant is considered "a subject of research" and not a patient. Their consent to participation in a clinical study must be based on fair and objective, even if unpromising, information about the nature and outcome of the study. To that end, before signing the ICF, the subject of research must be made aware of the nature, objectives, benefits, implications, risks, and inconveniences of the clinical study; the subject's rights and guarantees regarding their protection, especially the right to refuse to participate and the right to withdraw from the clinical study at any time without any resulting detriment and without having to provide any justification; the conditions under which the clinical study is to be conducted, including the expected duration of the subject's participation in the clinical study; and the possible treatment alternatives, including the follow-up measures if the participation of the subject in the clinical study is discontinued.[6]

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5 Surbhi Grover et al., "Clinical Trials in Low and Middle-Income Countries – Successes and Challenges," *Gynecologic Oncology Reports* 19 (2017): 5–9.

6 Chapter V, Article 29, Regulation (EU) 536/2014.

Research subjects may gain some personal treatment benefits from participating in a clinical study. However, they must understand that they may not benefit from the clinical study; they may be exposed to unknown risks, and their participation is voluntary. Therefore, they must be given sufficient time to consider the risks and benefits of participating in a clinical study before giving their voluntary consent. In addition, potential subjects must be given ample opportunity to enquire about details of the trial, and they must not be "lured" into consenting by false or incomplete information related to the study.[7]

2.3. Legal Aspects of Informed Consent in a Clinical Study

The recorded history of the first clinical studies goes back to the Biblical descriptions in 500 BC.[8] In the early evolutionary period, studies were usually concerned with dietary therapies. Still, as soon as the basic approach of the clinical study was defined in the 18th century, efforts were made to refine the design and statistical aspects. These were immediately followed by changes in the regulatory and ethics milieu.[9] However, only after the 1947 judgment by the War Crimes Tribunal at Nuremberg was a new set of standards of ethical medical behavior for the post-World War II human rights era established. Among other requirements, the Nuremberg Code verbalises the requirement of *voluntary informed consent* of the human subject. The principle of voluntary informed consent protects the right of the individual to control their body. That meant that the participant should have the legal capacity to give consent; they should be so situated as to be able to exercise free power of choice without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable them to make an understanding and enlightened decision. This means that before giving consent, the participant must be well informed about the nature, duration,

7 Para. 3.3a of WHO Guidelines for good clinical practice (GCP) for trials on pharmaceutical products, *WHO Technical Report Series*, no. 850 (1995), Annex 3.

8 Roger Collier, "Legumes, Lemons and Streptomycin: A Short History of the Clinical Trial," *Canadian Medical Association Journal* 180, no. 1 (2009): 23–4.

9 Arun Bhatt, "Evolution of Clinical Research: A History Before and Beyond James Lind," *Perspectives Clinical Research* 1, no. 1 (Jan–Mar 2010): 6–10 (6).

and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon their health or person which may possibly come from their participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. During the experiment, the human subject should be at liberty to bring the experiment to an end if the subject has reached the physical or mental state where continuation of the experiment seems impossible.[10]

This Code also recognizes that the risk must be weighed against the expected benefit and that unnecessary pain and suffering must be avoided. The doctors should avoid actions that injure human patients and should terminate the experiment when its continuation is likely to result in injury, disability, or death to the experimental subject. Every participant must be aware of the possible risks of side effects and unwanted events during the clinical study and that the experimental treatment may be ineffective for certain participants.

The Nuremberg set of guidelines on medical/clinical research on humans soon became an integral part of the International Covenant on Civil and Political Rights of the United Nations, prohibiting the participation of a human subject in a clinical study without their free consent (Article 7).[11] The Helsinki Declaration also places special attention on the informed consent principle. Hence, Article 24 states that any medical research on human subjects requires the researcher to adequately inform the participant about the study's purpose, methods, and anticipated benefits and potential risks, including its inconveniences.[12] However, the Declaration allows for the study involving human subjects without their informed consent as long as the physical or mental condition that prevents them from consenting is a necessary characteristic of the studied population (Article 29).

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10 Nuremberg Code (1947).

11 United Nations Covenant on Civil and Political Rights, 1967, accessed February 5, 2024, https://treaties.un.org/doc/Treaties/1976/03/19760323%2006-17%20AM/Ch_IV_04.pdf.

12 World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects, WMA General Assembly, Helsinki, Finland, June 1964 and amended in 1975, 1983, 1989, 1996, 2000, 2002, 2004, 2008, and 2013.

CIOMS Guidelines of 2002 are more flexible in comparison to the Helsinki Declaration in terms of the request for informed consent by giving discretionary rights to ethics committees to decide about exceptions from this fundamental principle. Thus, according to Guideline 4, in all biomedical research involving humans, the investigator must obtain the voluntary informed consent of the prospective subject or a legally authorized representative per applicable law. The decision to participate in research must be made by a competent individual who has received the necessary information, has adequately understood the information, and has arrived at a decision without having been subjected to coercion, undue influence, inducement, or intimidation. A competent individual is entitled to freely choose whether to participate in research. Thus, informed consent protects their freedom of choice and respects their autonomy. In case an individual has limited capacity to give adequate informed consent (young children, adults with mental or behavioral disorders, and individuals unfamiliar with medical concepts and technology), their decision is complemented by an independent ethical review committee (Guidelines 13, 14, 15). The prospective subject's ability to understand the information necessary to give informed consent depends on their maturity, intelligence, education, and belief system. They should be given sufficient time and resources to reach a decision. As a general rule, the subject should sign a consent form before participating in research. Exceptionally, the ethical review committee may approve a waiver of the requirement of a signed consent form if the research carries no more than minimal risk attached to routine medical or psychological examination. This means that waiver of informed consent is to be regarded as unorthodox and exceptional and must, in all cases, be approved by an ethical review committee.[13]

Intending to set up general standards for performing biomedical research on humans, the WHO approved the Good Clinical Practice Guide in 1995, thus acknowledging the legal and ethical principles of the Helsinki

[13] Council for International Organisations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002): Guideline 4, accessed February 5, 2024, https://ec.sut.ac.th/File/pdf/1%202_CIOMS_Guidelines_2002.pdf.

Declaration and CIOMS Guidelines.[14] Next to highlighting the voluntary and entirely consensual nature of participation in a clinical study, the GCP Guide also appeals to careful consideration of obtaining informed consent from certain groups of people whose participation is (un)justly motivated by expectations of benefits or a retaliatory response from senior members of the hierarchy in case of refusal to participate. Those are primarily members of a group with a hierarchical structure, such as medical, pharmacy, and nursing students, hospital and laboratory personnel, pharmaceutical industry employees, and armed forces members. Other vulnerable groups whose consent also needs special consideration include patients with incurable diseases, people in nursing homes, prisoners or detainees, the unemployed or people with a very low income, patients in emergency departments, some ethnic and racial minority groups, the homeless, nomads, and refugees. The process of recruiting should be carefully reviewed by the ethical review committee.[15] In addition, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), in 1996, introduced the Guideline for Good Clinical Practice to ensure recognition of collected data from clinical studies by the regulatory authorities in the EU, Japan, and the USA. Hence, Article 2.9 states that "Freely given informed consent should be obtained from every subject prior to clinical trial participation." Furthermore, Article 4.8.10 itemizes all the necessary information that the participant (human subject) should be provided with through informed consent discussion and the written informed consent form. In comparison to informed consent in other medical treatments, the Guideline provides for, in Article 4.8.11., a higher level of transparency and protection of the participants' integrity by allowing them to:

> receive a copy of the signed and dated written informed consent form and any other written information provided to the subjects." Furthermore, during the subject's participation in the study, their legally acceptable representative

[14] World Health Organisation Guidelines for good clinical practice (GCP) for trials on pharmaceutical products, WHO Technical Report Series, no. 850, 1995, Annex 3.

[15] WHO GCP Guide, para. 3.3.

"should receive a copy of the signed and dated consent form updates and a copy of any amendments to the written information provided to subjects.[16]

According to the Oviedo Convention and its Protocols,[17] informed consent is not defined as an unconditional right, having been limited by the interest of public safety, the prevention of crime, the protection of public health or by the protection of the rights and freedoms of others (Article 26(1)). Those are, however, exceptional circumstances that rarely derogate the predominantly humanistic policy of the Convention, which is the protection of the physical and mental integrity and identity of a human being.

2.4. Ethical Aspects of Informed Consent in a Clinical Study

Every medical or clinical study that includes human participation should be designed and conducted to achieve scientific integrity and follow ethical principles to protect its participants' health, safety, and well-being.[18] Hence, defining specific criteria when planning a clinical study is important. Various ethical standards and guidelines guarantee the protection of safety, dignity, self-determination, and confidentiality of research participants' personal information. The ten-point Nuremberg Code emphasizes the importance of sound scientific research protocol and informed consent. These criteria include the selection of patients who will participate in a concrete clinical study. A fundamental principle of clinical study is inclusion and exclusion criteria that enable the plausibility of research results. Factors that enable participation represent inclusion criteria, while a person who meets certain exclusion criteria cannot participate in a clinical study. These factors are, among others, age, sex, type and severity of disease, earlier treatment, and other medical conditions/diseases. It is important to note that inclusion and exclusion criteria are not intended to disable participation in a clinical study based on personal reasons but to identify a group of patients

16 Pantović and Zrnić, "Ethical, Clinical and Legal Aspects," 125.

17 European Council's 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 (ETS No. 164) and its Protocols, Oviedo, 4 April 1997, entered into force 1 December 1999, accessed February 6, 2024, https://www.coe.int/en/web/bioethics/oviedo-convention.

18 Hyoung Shin Lee, "Ethical Issues in Clinical Research and Publication," *Kosin Medical Journal* 37, no. 4 (2022): 278–82, https://doi.org/10.7180/kmj.22.132.

who stand the best chance of successful treatment and to provide the safety of applied therapy. In addition, well-defined criteria help investigators get a clear answer to the study question. With that in mind, a patient can withdraw from further participation in a clinical study at any time. It is sufficient to inform the assigned investigator about the decision and the reasons for dropping out. Although modern research ethics developed with the primary aim of protecting the safety and integrity of the participant, introducing strict scientific research protocols and informed consent, several reports on unethical medical studies conducted without informed consent on vulnerable research participants have been published since the early 1960s.[19]

3. Informed Consent in Clinical Studies in the Republic of Srpska

3.1. General Overview

The Republic of Srpska is a region where healthcare professionals work in environments with limited medical, human, and surgical resources. Such a setting greatly affects the research opportunities that involve human subjects. Although their legal and ethical guidelines closely follow the requirements and recommendations of various international medical and human rights associations (World Health Organisation, International Medical Association, United Nations, etc.) concerning clinical studies, still the double burden of disease in this lower-income region stresses a strong need for cost-effective and novel treatment plans that will be based on sustainable health research capacity.[20] Next to the legality of clinical studies performed in the Republic of Srpska that involve human subjects, there is the question of the ethicality of human experimentation that requires fully informed consent from research subjects. To that end, the authors of this paper share their scepticism with American anaesthesiologist Henry Beecher, who, back in 1966, welcomed the attempts of the federal government to insist on obtaining consent from research subjects as a worthy and necessary ideal but found that "obtaining consent in any fully informed sense was

[19] Henry K. Beecher, "Ethics and Clinical Research," *Bulletin of the World Health Organization* 79, no 4. (2001): 367–72.

[20] Such objectives are set up in the Quality Policy of UCC RS no. PM-06–002 of 15 September 2014.

highly unrealistic".[21] Instead, Beecher argued that the presence of an intelligent, informed, conscientious, compassionate, and responsible investigator offered the best protection for human research subjects.[22] In light of controversies that surround the voluntary participation of human subjects in clinical studies based on their informed consent or lack thereof, which are, according to Beecher, of universal nature, the authors will point out the most common legal and ethical challenges faced by both, investigators and study participants in the process of obtaining voluntary informed consent in the Republic of Srpska.

3.2. Informed Consent in Clinical Studies in the Republic of Srpska

As a low-income region, the Republic of Srpska invests insufficiently in public healthcare protection programmes, including biomedical research, to benefit science and society.[23] The budget for improving the quality of healthcare protection in the Republic of Srpska for 2024 amounts to KM 1.6 million (approx. EUR 750,000).[24] For comparison, neighboring Serbia, placed among lower-income countries, has become a land of opportunity for clinical research, with 322 clinical trials currently conducted inside its borders (oncology 68, gastroenterology 42, neurology 38, and cardiology 36).[25] International sponsors are responsible for 84% of ongoing trials. According to the Cromos Pharma report, reasons for recognizing Serbia as

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21 Jon Harkness, Susan E. Lederer, and Daniel Winkler, "Laying Ethical Foundations for Clinical Research," *Bulletin of the World Health Organization* 79, no. 4 (2001): 365–66.

22 Ibid.

23 For new drugs and treatment development in low- and middle-income countries/regions, see: Rakesh Jalali et al., "Drug Development in Low- and Middle-Income Countries: Opportunity of Exploitation?," *American Society of Clinical Oncology Educational Book* 42 (2022): 1–10; Grover et al., "Clinical Trials," 5–9; Adeel Khoja, Fiyyah Kayim, and Naureen Akber Ali, "Barriers to Conducting Clinical Trials in Developing Countries," *The Ochsner Journal* 19, no. 4 (2019): 294–5.

24 Budget of Republic of Srpska for 2024, National Assembly of Republic of Srpska, accessed February 11, 2024, https://www.narodnaskupstinars.net/?q=la/akti/bud%C5%BEet/bud%C5%BEet-republike-srpske-za-2024-godinu; Ljiljana Kovačević, "New Distribution of RS Budget: Planned Destruction of Healthcare, Culture, and Education," *Žurnal*, November 6, 2023, accessed February 11, 2024, https://zurnal.info/clanak/plansko-unistavanje-zdravstva-kulture-i-obrazovanja/26383.

25 Data obtained from clinicaltrials.gov.

a promising clinical research destination are multiple, starting from high recruitment rates and vast patient population (8.6 million inhabitants); moderate research costs and investigator fees; high-quality standards of clinical research; high-quality, accredited research units tailored to clinical trials; well-qualified, compliant, and experienced staff of GCP-certified investigators; enhanced regulatory framework and validated safety guidelines under Serbian law and the Medical Devices Agency; an increasing and ever-improving business infrastructure for clinical trials, including advancing medical devices; an opportunity to participate in clinical trials allows Serbian patients to have access to novel biologics, which are still limited under the state-funded supply programs, furthering the motivation.[26]

Compared to Serbia, it is unrealistic for the Republic of Srpska to expect any professionalism in clinical research that would result in a new or improved medical product/treatment. Without adequate investment in biomedical research and biotechnological innovations, it is difficult to expect continuous improvement in the quality and safety of healthcare protection.[27] In the past four years (2020–2023), only a few clinical studies were undertaken, usually non-interventional and non-invasive, representing little to no risk to the human subject, by an internal medical professional for scientific purposes (academic career advancement), while others were sponsored by external partners.[28] Due to resource limitations, many of these studies were enabled by engaging patients for their personal benefit (mostly terminally ill patients) or obtaining consent from the study subject based on selective and limited information. These observations are only

[26] Cromos Pharma is an agency which offers partnership in international clinical research projects. Hence, it launches clinical trials in the US, Central, Eastern Europe, Central and Southwestern Asia. It is interesting to note that Bosnia and Herzegovina (RS) is not among European destination countries (Bulgaria, Croatia, Czech Republic, Estonia, Georgia, Hungary, Kazakhstan, Latvia, Lithuania, Moldova, Poland, Romania, Russia, Serbia, Slovak Republic, Slovenia, Türkiye, Ukraine). "Serbia – A Land of Opportunity for Clinical Research," November 29, 2022, accessed April 2, 2024, https://cromospharma.com/serbia-a-land-of-opportunity-for-clinical-research/.

[27] Articles 11, 16 (21) of the Healthcare Protection Act (Official Gazette of Republic of Srpska, no. 57/22).

[28] According to the UCC RS Ethics Board Decision no. 01–19–65–2/24 of 14 February 2024, 79 clinical studies were performed on adult patients treated at the UCC RS from 2020 to 2023, and all were sponsored by an external partner (usually, pharmaceutical companies).

partially supported by documented facts since access to statistical data concerning clinical studies in the Republic of Srpska was either delayed or denied by the ethics boards/committees of healthcare institutions in charge of granting clinical studies on human subjects. However, unofficial statements from study participants and medical staff revealed many controversies regarding normative/ethical rules and principles and clinical practice.

3.2.1. Legal Aspects of Informed Consent in Clinical Studies in the Republic of Srpska

According to healthcare legislation of the Republic of Srpska, no clinical study can be performed without informed consent from the study subject, their guardian, or a legal representative. It is a fundamental legal and ethical requirement imposed on the investigator before conducting any human experiment. Henceforth, only a mature patient with legal capacity can participate in a clinical study after providing informed consent in writing. If the patient is a child or a person without legal capacity, written consent is provided by their parent, guardian, or legal representative.[29] The patient can provide their consent only after being informed about the purpose, procedure, expected results, possible risks, and unwanted outcomes of a clinical study. We see that the quality of information (e.g. fullness, sufficiency, adequacy, etc.) is not precisely defined, leaving the investigator the discretionary right to make casuistic estimates as to the quantity and quality of information sufficient to convince the subject to participate in a clinical study. Such normative imprecision as to the quality of information provides ample room for the unethical approach of the physician to the study patient, who, based on trust, will agree to virtually any request their physician may make. However, no patient is ready to jeopardize their health or risk their life for the sake of science, especially if it requires trying something no one knows would work.

A senior investigator must inform the potential study subject in writing about their right to refuse to participate in a clinical study and the right to terminate their participation at any time. This legal imperative can be interpreted as *in favorem vitae*, which means that the life and health of a human subject are more important than achieving results in clinical research. A human subject who suffers harm, damage, or loss at the expense of participating in a clinical study has a right to compensation. This

[29] Article 52 (1), (2) of HCPA RS.

means that the subject's consent does not have an *absolute* value and does not relieve the investigator from liability. However, there is a fine line between the subject's informed consent and the legal principle of *volenti non fit iniuria*. The most concrete legal ground for seeking informed consent arises from a contractual relationship between the subject and the investigator (ICF), preceded by the investigator providing *necessary* information to the subject. As a contracting party, the study subject is entitled to a copy of the signed ICF. Under the same Act, patients undergoing any other medical treatment/intervention are denied this right, indicating awareness of higher transparency of the study process. In addition, the RS legislator has restricted the patient's participation in a clinical study to drugs and medical assets, acting as *lex specialis* in relation to the Drugs and Medical Assets Act of Bosnia and Herzegovina as *lex generalis*.[30]

Key barriers that impede the study process are the lack of financial resources and skilled personnel, as well as regulatory and administrative issues. Accordingly, most funding for clinical studies comes from pharmaceutical companies established in the West.[31] The lack of qualified personnel is also apparent. Individuals with specialised training or experience in clinical studies often prefer to work abroad due to better opportunities, resulting in a continuous brain drain in the Republic of Srpska. Every request for a clinical study must be approved by the ethics board of the respective state-owned healthcare institution, which has developed a set of rules and guidelines to further arrange clinical studies.[32] Thus, for example, the University Clinical Centre of the Republic of Srpska (UCC RS) has adopted the Rulebook on the Performance of Clinical Studies (2016), which is accorded with the Rulebook on Clinical Study of Drugs and Medical Assets of Bosnia and Herzegovina[33] and Guidelines on Good Clinical Practice in Clinical Studies of BiH,[34] and is based on ethical and legal regulations of RS (BiH) and the international guidelines, such as the RS Healthcare Protection Act, the RS Social Welfare Act, the RS Records and

30 Article 52 (9) of HCPA RS.

31 Semi-official data obtained from the Ethical Committee of the Ministry of Health and Social Welfare of RS; email dated 12 February 2024.

32 Article 52 (3–11) of HCPA RS.

33 Official Gazette of Bosnia and Herzegovina, no. 4/10.

34 Official Gazette of Bosnia and Herzegovina, no. 19/12.

Statistical Research in Healthcare Protection Act, the Rulebook on Clinical Studies of Drugs and Medical Assets of BiH, the Code of Medical Ethics of PHI University Clinical Centre RS, the Code of Ethics for Nurses/Medical Technicians of PHI UCC RS, the Healthcare Protection and Safety at Work Policy of PHI UCC RS, and the Quality Policy of PHI UCC RS. However, unnecessary delays in ethical approval procedures and complex and unreasonably strict government regulatory systems turn informed consent into a mere formality.

Another legal loop that stands in the way of transparent and fair clinical research is the discretionary right of competent ethical authorities to decide *in meritum* when informed consent is not needed for the patient to participate in a clinical study, thus opening the door to manipulation with the requirement of full information before consenting to a clinical trial.

3.2.2. Ethical Aspects of Informed Consent in Clinical Studies in the Republic of Srpska

Medical research involving human subjects should be based on truth, promote and demonstrate scientific integrity, and follow ethical standards and guidelines to protect the study participants. Furthermore, the publication of clinical studies should be transparent and accessible to the general public. The investigator must possess full knowledge of ethical issues related to voluntary, informed and consensual participation of the participant in the clinical study to avoid misconduct allegations. Bound by the ethical principles of the Declaration of Helsinki, international ethical guidelines of biomedical research on humans, a clinical investigator in the Republic of Srpska must understand, respect, and protect the autonomy of will of the subjects, their right to self-determination and dignity, as well as the standards of good clinical practice set up to ensure and safeguard the safety and well-being of the patients and the authenticity of the study results.[35]

Most clinical studies in the Republic of Srpska are carried out on sick patients treated at the research healthcare institution.[36] According to the Rulebook, study participants should be tested with a new drug or medical asset intended to treat the patient's life-threatening primary disease.[37]

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35 Article 3 of the Rulebook on Clinical Studies, PHI UCC RS.

36 Semi-official data obtained from the Ethical Committee of the Ministry of Health and Social Welfare of RS, email dated 12 February 2024.

37 Article 4 of the Rulebook.

Due to the patient's already compromised health and previously obtained informed consent, it is very difficult to question the ethicality of the study procedure in relation to the voluntariness of the patient's participation. Furthermore, if there are unwanted effects on the patient's health due to the research therapy, it would be challenging to prove that the patient was not sufficiently informed about all the possible risks before giving consent. As mentioned before, publications of clinical studies are generally not transparent, the exception being scientific articles and theses in medicine, and the population interested in the study results cannot have open access to the study reports, contrary to the standard of publicity and transparency of clinical studies adopted by the ethics boards/committee of the Republic of Srpska research healthcare institutions and the Ministry of Health and Social Welfare.[38] Therefore, the authors have only managed to access fragmentary statistics about clinical studies carried out in healthcare institutions in the Republic of Srpska. Such a non-transparent policy prevents science and society from improving. Furthermore, unsatisfactory access to information about clinical trials largely affects the successful enrolment of participants into trials, especially those who volunteer for research. The right to information and informed consent in a clinical trial is a shared challenge among the neighboring countries, including Croatia. Although integrated into the EU, Croatia is still struggling with transparency of clinical trials, with the fewest registered trials in the EU Clinical Trials Registry (196 in 2017). This is the conclusion of Šolić et al., who assessed the transparency of clinical trials from the data available in the public domain and conducted an anonymous survey on a convenience sample of 257 patients. The authors further identified the possibility of benefiting from a new treatment as one of the main reasons Croatian patients participate in clinical studies. As for the negative practice of patients refusing to participate, the most prominent reasons are the fear of being a human guinea pig, worries they will be in the control group receiving a placebo and be thus left without help, and the feeling that joining a clinical trial means that all hope is lost. One of the problems contributing to this distrust is the lack of understanding of the methodology of clinical trials

[38] Article 29(4) of the Rules of Procedure of the Ethical Committee, Ministry of Health and Social Welfare of the Republic of Srpska, no. 11/04–052–8/17 of 16 March 2017.

and their purpose despite the information received during the informed consent procedure.[39]

Faced with the problem of open access to information, the authors had to concede to the data found in the public domain. Thus, having access to the online list of doctoral theses in research medicine defended at the Faculty of Medicine Banja Luka University (2020–2023), the authors selected six doctoral theses based on human clinical research.[40] Two theses resulted from an observational clinical study that required access to medical records of patients treated at the UCC RS. In one thesis, the investigator mentions that the request for performing a clinical study has been reviewed and granted by the Ethics Board of the UCC RS. Still, he does not list informed consent as one of the inclusion criteria, which is one of the essential requirements for the approval of the clinical study by ethics boards. The second thesis, however, includes informed consent among the inclusion criteria and its lack in the exclusion criteria. It is to be concluded that there is a notable conflict between the good clinical practice guidelines that allow for the exclusion of informed consent if the clinical study is based on analyzing statistical data and registers and the right to the confidentiality of research participants' personal information.

The remaining four theses were based on interventional clinical research. One included ten healthy subjects (control group) and 60 sick patients (experimental group). It was stated in the thesis that the participants were informed orally and in writing about the study protocol and the purpose of the research, and they confirmed their voluntary participation by signing the ICF. Based on the subject of the study (effects of the extract from the pomegranate peel on diabetes treatment), it is to be assumed that neither healthy nor sick participants were compensated for their voluntary engagement, and they were not insured against possible risks to their health. The authors have a valid reason to believe in the correctness of such an assumption, knowing that the investigator who initiates a clinical study

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39 Ivana Šolić et al., "Transparency and Public Accessibility of Clinical Trial Information in Croatia: How It Affects Patient Participation in Clinical Trials," *Biochemia Medica* 27, no. 2 (2017): 259–69, https://doi.org/10.11613/BM.2017.027.

40 The analyzed doctoral dissertations can be found on https://unibl.org/sr/vesti?q[by_kategorije][]=12 , accessed February 14, 2024.

for academic advancement is usually not adequately funded. Hence, the investigator has to count on the patients' goodwill to contribute to science without compensation. In such cases, the investigators must be well aware that the burden of responsibility lies entirely on them and that they should not abuse the relation of trust that they create with the patients. The practice has shown that participants who are harmed due to participation in a clinical study seldom take any legal action against the investigator, but their trust in the healthcare system is shattered.[41]

The remaining three theses also confirmed that they obtained an ethics board approval to carry out the clinical study. Still, knowing the requirements for obtaining the approval, IC being one of them, we cannot but notice certain inconsistencies in the research information that does not include informed consent in the inclusion criteria or does not reveal the process of recruiting participants. Likewise, the authors could not but notice the formal aspect of informed consent by carefully reading the recruitment protocol in the studied theses. Hence, in one thesis, it was stated that the candidates were first orally introduced to the purpose and aim of the subject research, and thus their verbal consent was obtained. Then, the candidates were given an informed consent form to read, understand, and sign, which they eventually did. It cannot be expected that an average person will fully understand the complexities and risks of medical research without the investigator's thorough and detailed explanation. Patient knowledge and awareness of and participation in clinical studies may be a special problem for smaller research communities such as the Republic of Srpska. There is little information on how well patients are informed about clinical trials in the Republic of Srpska. However, judging from the experience of low awareness of and adherence to common medical procedures among RS patients, a high level of information about clinical research, its risks and effects cannot be expected.

41 A case of a pregnant woman (identity known to the authors) who was invited to participate in a clinical study whose purpose was to define the stability of sugar values in pregnancy and who was informed by the investigator that there was no risk to her or her baby's life or health, but eventually resulted in unnecessary stress (the level of sugar in her blood was read as abnormally high, due to technical error of the test equipment) confirms the scepticism in the consent being obtained in the fully informed sense.

4. Conclusion

As a low-income region, the Republic of Srpska human research medicine struggles with many legal, social, personnel, economic, and ethical challenges. The investigators have a legal and moral obligation to respect and protect the safety and interests of the study participants, which implies fully informing the study subject of the nature, duration, purpose, methods, inconveniences, risks, and effects of the study. However, imprecision in legal defining the quality of information has enabled the supremacy of the investigator's discretionary over the subject's consent based on full and objective information. Clinical research can only be conducted when the objective outweighs the participant's risk.

The first level of protection of the subject's interests should be the investigator, through an open, sincere and responsible approach in the informing process, which does not stop with obtaining the subject's informed consent but lasts throughout the clinical study. By law, the surveillance pyramid starts with the investigator, continues to the ethics board and ends with the ethics committee. However, such a legal setting is severely ignored and nonfunctional. In addition to legal enforcement weaknesses, research medicine in the Republic of Srpska faces a very tedious red tape of unnecessarily strict regulatory mechanisms, including unreasonably delayed ethical approval procedures and non-transparency of study publications.

Meagre funding of clinical studies in the Republic of Srpska represents an open call to trained and skilled investigators and researchers to invest their knowledge elsewhere, reducing the study opportunities for the benefit of the Republic of Srpska population, thus impeding the advancement of healthcare protection in the Republic of Srpska. In opposition to overregulation stands non-regulation of certain research medical fields, such as healthcare technologies, reducing the scope of clinical studies to drugs and medical assets.

Currently, most clinical studies in the Republic of Srpska are funded by pharmaceutical companies based in the West, who show interest in placing their medical products in the Republic of Srpska healthcare market at unaffordable costs. On the other hand, Republic of Srpska researchers, faced with a severe shortage of funding and pressed by the requirements of academic advancement, find themselves in the position to either give up

on their academic careers (which they rarely do) or to risk their subjects' health or life by not presenting them with the "worst" possible scenarios, but instead showing them the variety of problems encountered to obtain their consent. However, according to the Republic of Srpska laws, even when informed consent has been obtained, it does not have absolute value; it does not relieve the investigator of any responsibility, which appears fair for obtaining consent without providing complete and objective information to the study subject.

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Informed Consent for the Use of AI in the Process of Providing Medical Services

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medical AI

Abstract: It has been for several years now that physicians use medical devices based on artificial intelligence (AI) in their professional practice. The use of these tools makes health services more personalized, tailored to the individual characteristics and needs of the patient. There is also a technological possibility for AI systems to provide patients with information regarding their health condition and treatment methods. The use of medical devices equipped with AI creates new types of risk, including the risk of algorithmic error, the risk of cyber-attack, and the risk of algorithmic mismatch (false-positive or false-negative results). Most patients do not know these tools, so not everyone will trust them. Obtaining informed consent from the patient is a necessary condition for any medical intervention. This study attempts to answer the following questions: (1) Is there a legal possibility to provide AI with the ability to inform the patient about their health condition and proposed treatment methods?; (2) Does the unpredictability and opacity of AI behavior affect the scope of information that should be provided to the patient before medical intervention?; (3) What information should the physician provide to the patient for this consent to be considered informed?; (4) Should the patient always be informed that AI was involved in the diagnosis or therapeutic process? The presented study uses comparative law methodology. American, Belgian and German law are analyzed.

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1. Introduction

It has been for several years now that physicians use medical devices based on artificial intelligence (AI) in their professional practice. These tools make health services more personalized, tailored to the individual characteristics and needs of the patient. AI devices make it possible to gain insight into and then use biological relationships that would be impossible to discover otherwise.[1] The use of artificial intelligence creates new types of risk, including the risk of algorithmic error, the risk of cyber-attack, and the risk of algorithmic mismatch (false-positive or false-negative results). There is also a technological possibility for AI systems to provide patients with information regarding their health condition and treatment methods. Patients are not familiar with these tools, so not everyone will trust them. Medical intervention requires obtaining informed consent from the patient. This study will consider whether and to what extent consent to a medical intervention using AI should differ from the consent given to a medical intervention using traditional methods and analyze the legal possibility of AI providing information on the patient's health condition and proposed treatment methods.

2. Informed Consent

Obtaining patient consent is a *sine qua non* condition for the legality of any medical interventions.[2] According to Article 32(1) of the Act on the Professions of Physician and Dentist,[3] except for situations specified in the law, a physician may conduct an examination or provide other health services only after obtaining the patient's consent. Obtaining such consent legitimizes medical intervention taken by the healthcare provider, eliminating the unlawfulness of their actions, which would involve interference with personal rights in the form of bodily integrity. Consent shifts the risk of side effects and other undesirable treatment outcomes from the

1 Price Nicholson II, "Describing Black-Box Medicine," *Boston University Journal of Science and Technology Law* 21, no. 2 (Summer 2015): 347–8.

2 Rafał Kubiak, *Prawo medyczne* (Warsaw: C.H. Beck, 2010), 339.

3 Act on the Professions of Physician and Dentist of 5 December 1996, Journal of Laws 1997, No. 28, item 152.

physician to the patient. Case law has established[4] that a patient who consents to a surgical procedure takes the risk associated with the procedure, including its direct, typical, and ordinary consequences, about which they should be properly informed.

This raises the question of whether a patient can be held responsible for the risks associated with the unpredictability of artificial intelligence's actions as a result of giving consent. If so, to what extent and what information should the physician provide to the patient for the consent to be considered conscious, aware, and informed?[5] Should the patient always be informed that artificial intelligence is/will be involved in the diagnostic process or surgical procedure? How detailed should this information be? Should the patient be informed why the artificial intelligence made a specific diagnosis? What should the physician tell the patient about the artificial intelligence system?

An attempt to answer these questions should begin with a reminder that according to Article 9(2) of the Patient Rights and Patient Ombudsman Act,[6] the legislator obliges physicians to provide patients with comprehensive information about their health condition, diagnosis, proposed and possible diagnostic and treatment methods, foreseeable consequences of their application or omission, treatment results, and prognosis, within the scope of healthcare services provided by that physician. In the case of surgical procedures, patients are informed, among other things, about the method of performing the procedure and its risks.[7] Furthermore, according to Article 13(3) of the Medical Ethics Code, a physician is obliged to inform the patient not only about the planned diagnostic and therapeutic methods but also about all available ones, as well as about the risks associated with the use of any of them. Detailed explanation is required for the method

4 Polish Supreme Court, Judgment of 28 August 1972, Ref. No. II CR 196/72, OSN 1973, No. 5, item. 86.

5 Małgorzata Świderska, *Zgoda Pacjenta na zabieg medyczny* (Toruń: Dom Organizatora, 2007), 17.

6 Act on the Patient Rights and Patient Ombudsman of 6 November 2008, Journal of Laws 2009, No. 52, item 417, as amended.

7 Rafał Patryn and Sylwia Kiełbasa, "Zasady prawno-formalnego postępowania lekarza w kontekście świadomej zgody pacjenta i obowiązku zachowania tajemnicy lekarskiej," *Internetowy Przegląd Prawniczy TBSP UJ*, no. 4 (2015): 86, accessed April 24, 2023, https://ruj.uj.edu.pl/server/api/core/bitstreams/9dcdbb53-72ca-48a6-9c91-c9044da91a86/content.

proposed by the physician, which they consider to be the most beneficial for the patient, as well as any complications resulting from the use of this method. From the above-mentioned provisions, it follows that, as a rule, a physician is obligated to inform the patient or their legal representative about the consequences and risks of a medical procedure in every case.[8]

3. Automatization of Providing Information and Consent

It is technologically possible to automate the provision of information about the patient's health condition and proposed treatment methods. It should be emphasized that information about the diagnosis differs from information on suggested treatment methods. In terms of the effective use of human resources, this solution seems beneficial. On the other hand, medical literature indicates that the relationship between physician and patient is one of the most important elements of an effective therapeutic process. In legal literature it is recognized that this relationship is characterized by trust[9] resulting from the patient's belief that the physician will treat them with due attention in every situation, not as the subject of medical procedures, but as a partner in the treatment process, sharing with them information about their health condition and responsibility for the final effect of treatment.[10] The quality of contact between the doctor and the treated person, the method of providing important information, the appropriate choice of words, the amount of time devoted to the patient, as well as the entire non-verbal side of the message addressed to the patient are important in the recovery process.[11] When providing information, physicians should take into account the patient's ability to understand the information they provide. This depends on patient's intellectual capabilities and their emotional state, but also on other circumstances surrounding the provision of information.[12] Artificial intelligence, unlike

8 Anna Stychlerz, "Zakres informacji przekazywanych pacjentowi," *Forum Medycyny Rodzinnej* 2, no. 6 (November 2018): 471–3.

9 Świderska, *Zgoda Pacjenta*, 99.

10 Justyna Szpara, "Prawo do informacji medycznej w relacjach pacjenta z lekarzem," *Prawo i Medycyna* 1, no. 4 (Winter 1999): 135.

11 Ewa Ogłodek, Danuta Moś, and Aleksander Araszkiewicz, "Zasady kontaktu terapeutycznego lekarza z pacjentem," *Zdrowie Publiczne* 119, no. 3 (Winter 2009): 331.

12 Brian Pickering, "Trust, but Verify: Informed Consent, AI Technologies, and Public Health Emergencies," *Future Internet* 14, no. 5 (May 2021): 20; Jan Ciechorski, "Glosa do wyroku Sądu Apelacyjnego w Gdańsku z dnia 28 listopada 2012, V ACA 826/12," *Palestra*, no. 1–2

a physician, cannot take into account circumstances related to the patient's emotions.

The World Health Organization has published guidance on Ethics and governance of artificial intelligence for health. The WHO has introduced six ethical principles for the design and use of AI. The first one is the protection of human autonomy. According to this principle, humans should maintain full control over AI and the health care system, and make medical decisions independently.[13] The EU legislator also emphasizes respect for human autonomy and the need to supervise AI. According to Article 4a of the draft of Artificial Intelligence Act, AI should be developed and used as tools that serve people, respect human dignity and personal autonomy and operate in a way that humans can appropriately control and supervise.[14] The principle of human autonomy was also indicated in the draft convention on artificial intelligence, human rights, democracy and the rule of law developed by the Council of Europe Committee on Artificial Intelligence.[15]

Giving an AI system (e.g. a virtual assistant) the competence to provide information on health and obtain consent for diagnostic and therapeutic activities would be contrary to the Act on the Professions of Physician and Dentist, i.e. articles 31–34. According to these regulations, only a physician can obtain consent from the patient and provide them with health services, except for nursing and midwifery services. Therefore, only by obtaining effective consent from the patient, after adequately informing them about the risks associated with the use of artificial intelligence (e.g. a surgical robot) and the proposed alternative treatment methods using the AI system,

(January/February 2014): 159; Marcin Kopeć, "Art. 31," in *Ustawa o zawodach lekarza i lekarza dentysty. Komentarz*, eds. Elżbieta Buczek et al. (Warsaw: Wolters Kluwer 2016), Lex/el.

13 World Health Organization, "Ethics and governance of artificial intelligence for health: WHO guidance," Geneva 2021, 25, accessed May 17, 2023, https://www.who.int/publications/i/item/9789240029200.

14 Amendments adopted by the European Parliament on 14 June 2023 on the proposal for a regulation of the European Parliament and of the Council on laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts (COM(2021)0206 – C9–0146/2021 – 2021/0106(COD)).

15 Draft Framework Convention on artificial intelligence, human rights, democracy and the rule of law, Committee on Artificial Intelligence (CAI), pp. 3–5, accessed May 15, 2024, https://rm.coe.int/-1493-10-1b-committee-on-artificial-intelligence-cai-b-draft-framework/1680aee411.

and subsequent performance of the procedure under the rules of medical practice, can the doctor be released from liability for interference with the patient's bodily integrity.

The use of artificial intelligence systems, chatbots and other tools to provide information and obtain consent for a procedure would require an amendment to the Act on the Professions of Physician and Dentist. In my opinion, this is unacceptable due to the key role of the relationship between physician and patient. In most cases, there are several diagnostic and therapeutic methods. Artificial intelligence can be programmed to select specific treatment methods most beneficial to the software manufacturer or healthcare provider, and not necessarily to the patient. Moreover, more invasive methods may bring much better results. It appears that it will be much more difficult for the patient to consent to such a method when the option is presented by an IT system or a non-human. A physician who is in an interpersonal relationship with the patient, builds trust, and has authority, will be able to convince the patient to use such a method. Moreover, the doctrine indicates that the patient is usually a layperson and has no knowledge about the intricacy and complexity of the diagnostic and therapeutic process, hence it should be assumed that the physician should do everything to convince the patient to choose the medical method that is optimal in the physician's opinion.[16] They should be particularly careful when informing about the usefulness of various therapeutic methods when the patient prefers a method that is not very effective but is, for example, less invasive. Małgorzata Świderska points out that if a particular medical procedure is needed and the patient neglects the recommendations or refuses to undergo such a procedure, the physician is obliged to make repeated attempts to convince them to undergo this procedure if they are in direct contact with them.[17] Therefore, that obligation cannot be fulfilled by an artificial intelligence system. It can be argued that the physician, if they deem it helpful, can use an artificial intelligence system to convince the patient to use an effective treatment method and provide the patient with more comprehensive or better understandable information. However, they cannot stop there. In the author's opinion, they should do this only when

16 Świderska, *Zgoda Pacjenta*, 131.
17 Ibid.

traditional methods of providing information are insufficient, or at the express request of the patient.

4. Informing the Patient about the Use of AI in the Treatment Process

The analysis of the obligation to inform patients about the use of artificial intelligence systems shall take American doctrine as the starting point. Informed consent as a legal concept has its source in American jurisprudence and doctrine, from where, with minor modifications, it was adopted into Canadian jurisprudence, and later also into German, French, Swiss and English law.[18] American researchers were the first to analyze the obligation to inform patients about the use of AI in the treatment process. It is therefore probable that the doctrine, case law and legislation of other countries will also follow the solutions proposed by American researchers in matters of informed consent.

Gerald Cohen points out that in most cases, failure to inform the patient about the use of medical artificial intelligence will not constitute a violation of the right to give informed consent.[19] He points out that when considering whether a physician should inform a patient about the use of artificial intelligence, reference should be made to the reasonable medical practitioner standard, according to which the physician should provide information that a reasonable physician would provide in the same or similar circumstances. According to the author, the effects of artificial intelligence can be considered as an element of the physician's thought process. If one could lay open the thought process of a typical physician deciding which surgical technique to use or whether to recommend a particular patient to undergo a particular type of treatment, one would find a lot of potential inputs. A physician can rely on vague memories from college lectures, what other doctors during their residency did in such cases, the latest research in leading medical journals, the experiences with and outcomes of the last 30 patients the physician saw, etc. There is no doubt that a physician who fails to describe each of these steps of the reasoning does not violate the

18 Ibid., 17–8.

19 I. Glenn Cohen, "Informed Consent and Medical Artificial Intelligence: What to Tell the Patient?," *The Georgetown Law Journal* 108 (May 2020): 1442.

law on informed consent.[20] Therefore, the consent of a person who has not read this data may be considered informed if other requirements are met. Gerald Cohen also points out that one can rely on the reasonable patient standard. The author compares AI with pharmaceuticals approved by the Food and Drug Administration (FDA).[21] He believes that if doctors trust artificial intelligence as they trust FDA-approved drugs, and patients trust the doctor, then information about the use of an artificial intelligence system will not be required to obtain the patient's informed consent. It is necessary to create similar procedures for the approval of AI systems and to develop adequate indicators based on which the correctness of AI work could be checked.[22]

On the other hand, the use of an autonomous self-learning tool may cause anxiety in the patient, for example, because these are new technologies, previously unknown in medicine. The patient has greater or lesser confidence in the correctness of the doctor's thought process and awareness of the elements that make up this process. However, they do not have to trust an abstract entity such as an IT system, which they cannot see, imagine how it works, or compare it with other experiences. When traditional treatment methods are used, the patient usually believes that a physician who has graduated studies and specialization, based on research from medical journals and their own experience, makes a correct diagnosis and properly conducts the patient's therapy. This belief comes from experience because most people participated or accompanied others in at least several therapeutic and diagnostic processes. Almost every patient took medication at some time in their life. However, most patients do not have experience with artificial intelligence systems. Therefore, they should not be expected to trust AI in this area, especially when legal standards only partially regulate the principles of safe creation, testing and use of AI, and standards in this area are still being created.

American doctrine also advocates the view that a physician must always inform the patient about using an artificial intelligence system. They

20 Ibid.

21 The Food and Drug Administration is the authority responsible for the control and safety of drugs, supplements, cosmetics, medical devices, foods and biological materials in the United States. See: https://opieka.farm/fda/.

22 Cohen, "Informed Consent," 1443.

should explain the basic application of the technology and the basic nature of the algorithm. Moreover, they are obliged to clearly distinguish the roles that individual people will play during each part of the procedure from the roles played by artificial intelligence, a robotic system or a device.[23] Researchers dealing with medical law in the field of clinical trials also indicate that participation in an AI clinical trial without information can infringe on patient's right to self-determine who and what is involved in their care. At present, it is reasonable to assume that only humans, not AI systems, are involved in making their treatment decisions. However, many AI systems can now make human-like decisions that patients may reasonably expect to be made by clinicians.[24] Undoubtedly, it should be agreed that the patient should be informed only about the basics of how AI works, because explaining the technological details of the system's operations may negatively affect their decision-making process. Too much information can leave the patient confused. It is also important to let them know that the software will not work independently. There are two options for physician interaction with the system. The first is to determine the scope of activity, and the second is to support the AI in performing activities.

At the beginning of the analysis of the law in force in the EU Member States, it is necessary to point out the content of the draft Act on Artificial Intelligence. According to Article 52, healthcare providers shall ensure that AI systems intended to interact with natural persons are designed and developed in such a way that the AI system, the provider itself or the user informs the natural person in a timely, clear and intelligible manner that they are interacting with an AI system unless this is obvious from the circumstances and the context of use.[25] At this point, it is worth mentioning Belgian legislation. According to Article 8(2) of the Belgian Act on Patient's Rights, the information provided to the patient, necessary for consent,

[23] Daniel Schiff and Jason Borenstein, "How Should Clinicians Communicate With Patients About the Roles of Artificially Intelligent Team Members?," *AMA Journal of Ethics* 21, no. 2, (February 2019): 140.

[24] Subha Perni et al., "Patients Should Be Informed When AI Systems Are Used in Clinical Trials," *Nature Medicine* 29 (2023): 1891, https://doi.org/10.1038/s41591-023-02367-8.

[25] Amendments adopted by the European Parliament on 14 June 2023 on the proposal for a regulation of the European Parliament and of the Council laying down harmonized rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts (COM(2021)0206 – C9–0146/2021 – 2021/0106(COD)).

concerns the purpose, nature, degree of urgency, duration, frequency, contraindications, side effects and risks related to the procedure that are important for the patient, the need for further care, possible alternatives and financial implications. The information also covers the possible consequences in the event of refusal or withdrawal of consent and other circumstances considered important by the patient or physician, including the legal provisions that must be respected in relation to the intervention. The literature indicates that a physician cannot omit information provided in Article 8 of the Act on Patient Rights if they use an artificial intelligence system. The information provided to the patient must be the same as if the doctor used methods not based on the operation of artificial intelligence systems. This does not mean that the patient should be informed about the use of AI or how it works.[26] Wannes Buelens points out that artificial intelligence and robots must be seen only as tools in the hands of a physician to provide health care, just like a scalpel or an MRI scanner. Generally, a physician is not obliged to inform a patient about every tool they use during treatment. The mere failure to inform the patient about the use of AI does not make them negligent if they provide the patient with information about their condition, prognosis, suitable health behavior, the purpose and nature of the treatment, significant risks and possible alternatives.[27]

The Polish legislator and case law have not indicated the scope of information that a patient should be given by a physician when undergoing treatment with the use of artificial intelligence. This problem was raised in the *White Paper of AI in Clinical Practice*, which is a self-regulation of medical facilities regarding artificial intelligence.[28] This document indicates that it is not the mere fact of using artificial intelligence that makes

[26] Wannes Buelens, "Robots and AI in the Healthcare Sector: Potential Existing Legal Safeguards against a(n) (Un)Justified Fear for 'Dehumanisation' of the Physician-Patient Relationship," in *Artificial Intelligence and the Law*, eds. Jan De Bruyne and Cedric Vanleenhove (Cambridge: KU Leuven Centre for IT&IP Law Series, Intersentia, 2021), 560.

[27] Ibid., 561.

[28] This document was created by the Polish Federation of Hospitals, the AI in Health Coalition and the working group on artificial intelligence, and constitutes self-regulation of medical facilities in the field of artificial intelligence. The document has been approved by the government and is published on the government portal gov.pl, and the meetings of the scientific council were attended by the Director of the Department of Innovation at the Ministry of Health and the Deputy Director of the Department of Innovation at the Ministry of Health;

it necessary to inform and receive consent from the patient, but its importance in the process of treatment and diagnosis. The authors point out that if AI were only a minor factor among many other ones (e.g. the use of a "smart" thermometer as part of a transplant procedure), providing information about it would not seem necessary, as it should not be a factor influencing the decision of the average patient. However, the situation is different when AI has a significant impact on the process or nature of the health service provided – the patient should know and understand this impact, otherwise, their consent may be questioned.[29] If the medical professional agrees with the decision taken by AI on the treatment method and communicates this to the patient, it is necessary to inform the patient about the role of artificial intelligence.[30] This solution seems correct. Informing the patient about the characteristics of each tool used to provide health services is pointless. Contrary to expectations, too much information provided to the patient reduces, rather than increases, awareness of their medical situation and the proposed treatment. Therefore, the patient should receive from the physician, even when using AI, only information that is important in the decision-making process to undergo treatment. This solution complies with case law, doctrine and standards functioning in the medical community.

The soft law developed in Poland by the medical community does not specify what information should be provided to the patient to obtain their consent. This problem was analyzed by German researchers at the University of Ulm. They created guidelines that can be successfully applied within the European Union countries and beyond the UE, including the USA. In the researcher's opinion, eight new pieces of information should be added to the information classically provided to the patient, i.e. they should describe the input and output data of the AI, explain the AI training method and how it generates output data by learning from examples, explain the risks of cyber attack, algorithmic error and algorithmic mismatch (false

access to the document: https://aiwzdrowiu.pl/wp-content/uploads/2022/06/BIA_A-KSIE_GA_AI-W-ZDROWIU_2022.pdf.

29 Paweł Kaźmierczyk, ed., *Biała Księga AI w praktyce klinicznej* (Warsaw: AI w zdrowiu, GRAI, PFSZ, 2022), 45, accessed May 17, 2024, https://aiwzdrowiu.pl/wp-content/uploads/2022/06/BIA_A-KSIE_GA_AI-W-ZDROWIU_2022.pdf.

30 Ibid.

positive or false negative results), inform the patient of the right to a second opinion from a qualified physician and make the patient aware of how their data will be used outside the treatment process. The last element is the disclosure that the algorithmic decision will be taken without a physician's supervision.[31] Currently, the operation of AI systems uncontrolled by a human physician is allowed in the USA, but EU countries will not provide such a possibility according to the draft of the act on artificial intelligence.

It needs to be stressed that the risk of algorithmic error may result from the fact that algorithms sometimes contain racial biases because their training datasets are not representative and therefore do not take into account gender, race, ethnicity and other differences. There is also the risk of overfitting, which occurs when the underlying datasets are too homogeneous and therefore prone to generalization problems. Patients should be informed about possible errors in the training datasets and how these may affect the results of AI processes.[32]

The proposal of German researchers deserves approval. Providing the above information will enable the patient to make a conscious decision. It will also help avoid placing too much trust in AI and prevent patients from unjustified aversion to new technologies. Consent will be considered informed when the information is provided in a language accessible to the patient and adapted to their cognitive abilities. Providing correct information requires knowledge of the artificial intelligence system which the physician wants to use in the diagnostic and treatment process.

5. Conclusions

The above considerations lead to the following conclusions:

1) The use of AI systems to provide information and obtain consent for treatment would require an amendment to the current regulations. However, this is not justifiable given the key role of the relationship between the physician and the patient in the treatment process.

31 Franc Ursin et. al., "Diagnosing Diabetic Retinopathy With Artificial Intelligence: What Information Should Be Included to Ensure Ethical Informed Consent?," *Frontiers in Medicine* 8 (July 2021): 5, https://doi.org/10.3389/fmed.2021.695217.

32 Ibid., 4.

2) To information normally given to the patient, the physician should add: a description of the AI input and output data, an explanation of how the AI is trained and how it generates output data by learning from examples, a description of the risk of a cyberattack, a description of the risk of algorithmic error, a description of the risk of algorithmic mismatch (false-positive or false-negative results), indicating the patient's right to a second opinion of a qualified physician, indicating whether and how the patient's data will be used outside the treatment process, the disclosure that algorithmic decision will be supported without the supervision of a physician (if it is possible).
3) The information indicated in point 2 should be provided to the patient only when the AI has a significant impact on the process or nature of the health service provided – the patient should know and understand this impact, otherwise the awareness of their consent may be questioned.
4) When a physician intends to use a tool equipped with AI only as an aid, e.g. a thermometer or a blood pressure monitor, the patient does not have to be informed about this, because in the mass of irrelevant data, they might not understand the issues that are of relevance for them.

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Fault–Based Liability for Medical Malpractice in the Age of Artificial Intelligence: A Comparative Analysis of German and Greek Medical Liability Law in View of the Challenges Posed by AI Systems

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Abstract: The rapid developments in the field of AI pose intractable problems for the law of civil liability. The main question that arises in this context is whether a fault-based liability regime can provide sufficient protection to victims of harm caused by the use of AI. This article addresses this question specifically in relation to medical malpractice liability. Its main purpose is to outline the problems that autonomous systems pose for medical liability law, but more importantly, to determine whether and to what extent a fault-based system of medical liability can adequately address them. In order to approach this issue, a comparative examination of German and Greek law will be undertaken. These two systems, while similar in substantive terms, differ significantly at the level of the burden of proof. In this sense, their comparison serves as a good example to "test" the adequacy of the fault principle in relation to AI systems in the field of medicine, but also to illustrate the practical importance that rules on the allocation of the burden of proof can have in cases of damage caused by the use of AI. As will eventually become apparent, the main problem appears to lie not in the fault principle itself, which, for the time being, at least in the form of objectified negligence, seems to protect the patient adequately, but mainly in the general rule on the allocation of the burden of proof, which is precisely why the fault principle ends up working to the detriment of the patient.

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1. Introduction

"If 2023 was the year that AI finally broke into the mainstream, 2024 could be the year it gets fully enmeshed in our lives – or the year the bubble bursts."[1] The *Los Angeles Times*' pithy statement may seem like an exaggeration, but there is certainly some truth to it: artificial intelligence is entering the mainstream and it looks as if it may soon become fully entrenched in our lives. AI has long ceased to be the stuff of science fiction; autonomous systems, algorithms, big data, and robots are terms that have begun to enter our everyday vocabulary. This is because they now describe a reality that touches almost every area of our lives.

The same is true in the field of medicine, where the use of artificial intelligence is constantly increasing[2] and it is already part of everyday medical life.[3] In diagnostic medical imaging, especially in radiology, where artificial intelligence is to some extent established, there is extensive use of AI-based diagnostic systems to assess/evaluate CT images or to calculate the dynamics of tumor growth.[4] In histopathology, for example, artificial neural networks can classify tissue areas into tumor-suspect and non-tumor-suspect areas, enabling the physician to focus their attention exclusively on the areas labelled as suspicious.[5] An AI software can determine radiological findings, or diagnose the presence of skin cancer. Data synchronization (comparison of the individual data of a patient with a particular disease with the course/

1 Brian Contreras, "What AI will bring in 2024: 4 predictions," *Los Angeles Times*, January 2, 2024, accessed February 16, 2024, https://www.latimes.com/business/technology/story/2024-01-02/ai-predictions-2024-competency-tests-election-ads-bankruptcies.

2 Herbert Zech and Isabelle Céline Hünefeld, "Einsatz von KI in der Medizin: Haftung und Versicherung," *MedizinRecht* 41, no. 1 (January 2023): 1.

3 Lukas Ströbel and Robert Grau, "KI-gestützte Medizin-Apps," *Zeitschrift für Datenschutz* 12, no. 11 (November 2022): 600; Susanne Beck, Michelle Faber and Simon Gerndt, "Rechtliche Aspekte des Einsatzes von KI und Robotik in Medizin und Pflege," *Ethik in der Medizin* 35, no. 2 (April 2023): 249.

4 See: Anna Lohmann and Annika Schömig, "'Digitale Transformation' im Krankenhaus. Gesellschaftliche und rechtliche Herausforderungen durch das Nebeneinander von Ärzten und Künstlicher Intelligenz," in *Digitalisierung, Automatisierung, KI und Recht – Festgabe zum 10-jährigen Bestehen der Forschungsstelle RobotRecht*, eds. Susanne Beck, Carsten Kuche and Brian Valerius (Baden–Baden: Nomos 2020), 362 et. seq.

5 Sebastian Försch et al., "Künstliche Intelligenz in der Pathologie," *Deutsches Ärzteblatt* 118, no. 12 (March 2021): 201 et seq.

progression of similar cases over decades, including secondary diagnoses[6]) makes it possible to identify patterns that are extremely difficult for humans to recognize.[7] Similarly, the contribution of artificial intelligence in neurology and cardiology,[8] and even in surgery,[9] is not negligible, while it has also contributed to the development of systems medicine and the gradual transition to a personalized provision of medical services.[10] Given the new challenges involved in everyday treatment, especially due to limited human resources,[11] the use of AI seems to promise better individual healthcare, as it opens new possibilities for diagnosis and treatment, disease prevention, and prognosis. Ultimately, it is likely that it will contribute significantly to a longer and more autonomous life,[12] benefiting not only individual patients but also the health system as a whole.[13]

2. The "Black–Box Effect" and the Problems It Poses for Medical Liability Law

Despite all their benefits, we cannot ignore the problems that autonomous systems may pose for medical liability law. For the first time in history, we are confronted with digital systems that can decide on their own "acts and omissions," without full predictability and control on the part of their manufacturer, programmer, or user.[14] AI systems are autonomous in the sense that they can choose between several alternative forms of behavior, without

6 See: Christian Katzenmeier, "Haftung für Schäden durch KI in der Medizin," in *Die Macht der Algorithmen*, eds. Thomas Grundmann et al. (Baden–Baden: Nomos, 2023), 73.

7 Beck, Faber and Gerndt, "Rechtliche Aspekte," 249.

8 Katzenmeier, "Haftung für Schäden," 74.

9 See: Beck, Faber and Gerndt, "Rechtliche Aspekte," 250.

10 Christian Katzenmeier, "Big Data, E-Health, M-Health, KI und Robotik in der Medizin. Digitalisierung des Gesundheitswesens – Herausforderung des Rechts," *Medizinrecht* 37, no. 4 (April 2019): 259 et. seq.

11 Jan–Robert Schmidt, "Die Auswirkungen der Nutzung von KI-Software auf die ärztliche Haftung," *Gesundheitsrecht* 22, no. 6 (June 2023): 341; Ströbel and Grau, "KI-gestützte Medizin-Apps," 600.

12 Katzenmeier, "Big Data," 259; Katzenmeier, "Haftung für Schäden," 71.

13 Beck, Faber and Gerndt, "Rechtliche Aspekte," 249.

14 Gerhard Wagner, "Verantwortlichkeit im Zeichen digitaler Techniken," *Versicherungsrecht* 71, no. 12 (December 2020): 724.

this choice being predetermined (i.e. pre-programmed).[15] While they operate algorithmically, they differ from typical software, which "behaves" in a strictly deterministic way,[16] in the sense that the programmer gives the algorithms a specific structure and methodology, but they then proceed on their own to deduce the results/conclusions.[17] The autonomy of AI systems in that sense is manifested in two ways: *ex-ante*, it appears as limited predictability ("Vorhersehbarkeit"), which makes it impossible to fully control the system, something that in turn creates, at least in theory, the risk of damage due to unforeseen circumstances.[18] *Ex-post*, it appears as limited explainability ("Erklärbarkeit") of the system's behavior and the causes that led to it, and ultimately of the causes that led to the resulting damage.[19] It is precisely due to this lack of transparency around the decision-making processes that AI systems are referred to as "black boxes,"[20] which gives rise to the idea of the "black–box effect."[21]

The "black-box effect" raises the crucial question as to whether the current liability law, which is human-centered by definition,[22] can effectively address the damage caused by the use of autonomous systems in the context of the provision of medical services. To answer this question,

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15 See in more detail: Christiane Wendehorst and Yannic Duller, "Safety- and Liability-Related Aspects of Software," in *Civil Liability for Artificial Intelligence and Software*, eds. Mark A. Geistfeld et al. (Berlin: De Grutyer, 2023), 291 et. seq.

16 See: Julian Reichwald and Dennis Pfisterer, "Autonomie und Intelligenz im Internet der Dinge Möglichkeiten und Grenzen autonomer Handlungen," *Computer und Recht* 32, no. 3 (March 2016): 208, 211.

17 Schmidt, "Die Auswirkungen," 343.

18 Herbert Zech, "Risiken Digitaler Systeme: Robotik, Lernfähigkeit und Vernetzung als aktuelle Herausforderungen für das Recht," *Weizenbaum Series* 2, no. 1 (January 2020): 44 et seq., https://doi.org/10.34669/wi.ws/2.

19 Zech, "Risiken Digitaler Systeme," 44 and 48; see also: Herbert Zech, "Entscheidungen digitaler autonomer Systeme: Empfehlen sich Regelungen zu Verantwortung und Haftung," in *Verhandlungen des 73. Deutschen Juristentags* (Leipzig: C.H. Beck, 2020), 1: 44.

20 See, among others: Heinz–Uwe Dettling, "Künstliche Intelligenz und digitale Unterstützung ärztlicher Entscheidungen in Diagnostik und Therapie," *PharmaRecht* 41, no. 12 (December 2019): 635; Katzenmeier, "Big Data," 269; Wagner, "Verantwortlichkeit," 720; Luisa Mühlböck and Jochen Taupitz, "Haftung für Schäden durch KI in der Medizin," *Archiv für die civilistische Praxis* 221, no. 1–2 (February 2021): 183; Beck, Faber and Gerndt, "Rechtliche Aspekte," 254.

21 See in detail: Zech, "Risiken Digitaler Systeme," 42 et seq.

22 Katzenmeier, "Haftung für Schäden," 76.

we must first determine the specific problem that AI autonomy poses for medical liability law. Apart from certain high-risk autonomous systems, that might need to be specifically regulated,[23] self–learning autonomous systems are generally presumed to be safer than traditional technology.[24] As long as no human error (e.g. manufacturing error, etc.), is involved, they do not pose an increased risk, especially when their self-learning capabilities allow them to continuously improve their results, even at a personalized level. In this sense, the problem posed by the so-called autonomy risk ("Autonomierisiko")[25] at a substantive level, i.e. the impossibility of attributing (in the sense of "Zurechnung") the damage resulting from the autonomous operation of the system, does not seem to be the primary issue for the time being.

On the contrary, the issue of risk arises in cases of human errors that may occur during the construction, training, maintenance, and/or use of the system. Due to the "black-box effect," these errors are very difficult to detect and identify. The algorithms function correctly, but they may be "fed" with incorrect data, which are perpetuated, while the systems are running and interacting with other systems.[26] In theory, these types of damage are covered by the general liability law, since an accountability link between the damage and the respective human conduct can be established in such cases. The problem in practice, however, is that it is difficult to identify the exact cause of the damage, i.e. to detect the exact technical error that led to it. The "black-box effect" appears to create insurmountable evidentiary obstacles,

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23 For the so called high–risk systems, see Section 1 and 2 of Chapter III of the "AI–Act," i.e. the European Parliament legislative resolution of 13 March 2024 on the proposal for a regulation of the European Parliament and of the Council on laying down harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union Legislative Acts (COM(2021)0206 – C9–0146/2021 – 2021/0106(COD)), accessed May 28, 2024, https://europarl.europa.eu/doceo/document/TA-9-2024-0138_EN.pdf. Either way, as aptly noted, high-risk autonomous systems appear to be covered by the existing risk-based strict liability framework, see: Arbeitsgruppe "Digitaler Neustart", *Haftungsfragen der Künstlichen Intelligenz–Europäische Rechtsetzung*, Bericht vom 1. März 2023, 47–8, accessed February 10, 2024, https://www.justiz.nrw/JM/justizpol_themen/digitaler_neustart/zt_fortsetzung_arbeitsgruppe_teil_5/Bericht-Digitaler-Neustart_Haftung-bei-KI.pdf.

24 Mark A. Geistfeld et al., eds., *Civil Liability for Artificial Intelligence and Software* (Berlin, Boston: De Grutyer, 2023), 37.

25 See: Zech, "Risiken Digitaler Systeme," 44 et seq.

26 See: Katzenmeier, "Big Data," 269; Schmidt, "Die Auswirkungen," 343.

that are made even greater, given the practical difficulty of accurately separating the areas of responsibility of the various subjects associated with the autonomous system.[27] The autonomy risk therefore seems to indicate not so much the risk of damage, as the risk of ambiguity regarding the causes of the damage.

Things get even more complicated if one considers the open nature of many AI systems and their increasing interconnectivity,[28] which has the effect of further blurring the boundaries of the spheres of "responsibility" and "influence" of the various subjects involved in the network (such as manufacturers, developers, trainers, users, etc.).[29] The injured party is ultimately faced with extreme evidentiary difficulties concerning the cause of the damage,[30] as many systems, services, data supplies, and infrastructure facilities may coexist and interact at a network level.[31] Therefore, the resulting damage can always be attributed to many possible causes or errors. For the same reasons, similar difficulties seem to exist when it comes to proving the exact technical or human error responsible for the damage. To put it briefly, it is the very nature of AI and its particular features (limited predictability, complexity, opacity, and openness) that make it extremely difficult for the injured party to identify the cause or causes of the damage suffered, as well as to identify the responsible party (whether it is the autonomous system itself, or a specific human or legal entity, e.g. manufacturer, user, etc.).[32]

These problems appear to become even more complicated in cases of medical liability, where the injured party is also confronted with inherent evidentiary difficulties related to medical matters.[33] Thus, in addition to

27 Katzenmeier, "Big Data," 265.

28 In more detail see: Zech, "Digitale Risiken," 47 et. seq.

29 Wagner, "Verantwortlichkeit," 725.

30 See: Zech and Hünefeld, "Einsatz von KI," 5. Gunther Teubner, "Digitale Rechtssubjekte? Zum privatrechtlichen Status autonomer Softwareagenten," *Archiv für die civilistische Praxis* 218, no. 2–4 (August 2018): 201 et seq.; Wagner, "Verantwortlichkeit," 717, 734; Gerald Spindler, "Medizin und IT, insbesondere Arzthaftungs- und IT-Sicherheitsrecht," in *Festschrift für Dieter Hart. Medizin – Recht – Wissenschaft*, ed. Christian Katzenmeier (Berlin: Springer Verlag, 2020): 581, 583, 584, 591, 597; Mühlböck and Taupitz, "Haftung für Schäden," 183 et seq.

31 Wagner, "Verantwortlichkeit," 725.

32 See: Geistfeld et al., *Civil Liability*, 19; see also: Beck, Faber and Gerndt, "Rechtliche Aspekte," 254.

33 On this issue see: Erwin Deutsch and Andreas Spickhoff, *Medizinrecht. Arztrecht, Arzneimittelrecht, Medizinprodukterecht und Transfusionsrecht* (Berlin: Springer Verlag, 2014), 740 et seq.

these, the patient must also overcome the obstacle of the "black-box effect" in order to trace the exact cause of their damage, being therefore obliged to prove both a specific human error in the use of the system (as well as who committed it) and the causal link between the error, the output of the system, and the damage sustained.[34] Hence, in addition to their information deficit regarding medical issues, the patient now has to cope with a respective deficit in relation to highly complicated technical issues of artificial intelligence (which, given the "black-box effect," are extremely difficult even for the experts themselves). As a result, their evidentiary difficulties are now intensified, as they will have neither sufficient technical knowledge to meet the respective burden of proof, nor the financial means to make up for this deficit of knowledge. This correspondingly reduces the chances of a lawsuit for medical malpractice succeeding – precisely to the extent that the fault principle applies along with the general rule on the allocation of the burden of proof.

It is clear that the typical risks inherent in AI do not primarily increase the potential for damage, but rather make it more difficult to clarify and prove causal links in the event of damage.[35] Its autonomy does not imply higher risk but increased evidentiary difficulties. In other words, the "black-box effect" poses, at least for the time being, mainly evidentiary problems. The main question that arises is whether and to what extent a fault-based medical liability system, operating in conjunction with the general rule on the allocation of the burden of proof,[36] can deal with these problems effectively without necessitating legislative changes, especially in the form of a general risk-based strict liability. The following *de lege lata* comparative examination of German and Greek law was undertaken in order to address this problem.

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34 In fact, in these cases the error in the use/operation of the system will also be a medical error. See also: Wendehorst and Duller, "Safety," 293.

35 See: Digitaler Neustart, *Haftungsfragen*, 3.

36 See: Ivo Giesen, "The Burden of Proof and other Procedural Devices in Tort Law," in *European Tort Law 2008*, eds. Helmut Koziol and Barbara C. Steininger (Vienna: Springer Wien New York, 2009), 50.

3. Medical Liability Regime under Current Law: A General Overview

First of all, it must be pointed out that the following analysis focuses on the problem of the liability of the physician/hospital for damage caused by the use of autonomous systems in the provision of medical services. The related issue of the liability of other persons, in particular of the manufacturer, is of great practical importance, especially in view of the debate on who should be liable in cases of damage caused by AI, but remains beyond the scope of the present study, which is to examine the problem of medical liability arising from the use of AI. Similarly, the study does not deal with *de lege ferenda* solutions to the problem nor with constructions such as legal e-personality, for its sole purpose is to identify whether and to what extent systems based on the fault–principle can effectively address the relevant problems.

Both in German and Greek law, medical liability can arise from contract and tort law; thus, the physician who breaches their duty of care is liable not only contractually, but also in tort. Both legal systems hence refer to concurrent claims of the patient.[37] Accordingly, in both systems medical liability arises on the basis of subjective liability. This means that the physician can only be held liable for a culpable breach of duty. The following analysis presents an overview of the basic characteristics of German and Greek medical liability laws (contractual and tort), to "prepare the ground" for specifically addressing the problem of medical liability from the use of AI below.

3.1. Liability Regime under German Law

3.1.1. General Overview: Medical Liability and Breach of Medical Standards

As mentioned, under German law, the physician bears both contractual and tort liability. Thus, under the treatment contract ("Behandlungsvertrag"),[38]

[37] For German law, see, among others: Deutsch and Spickhoff, *Medizinrecht*, no. 298 et. seq; Bernd-Rüdige Kern and Martin Rehborn, in *Handbuch des Arztrechts*, ed. Adol Laufs, Bernd-Rüdige Kern, and Martin Rehborn (München: C.H. Beck, 2019), § 92 no. 22; Dieter Medicus and Stephan Lorenz, *Schuldrecht Besonderer Teil* (München: C.H. Beck, 2018), § 32 no. 21. For Greek law: Κατερίνα Φουντεδάκη, *Αστική Ιατρική Ευθύνη* [hereinafter: Katerina Fountedaki, *Civil Medical Liability*] (Athens: Sakkoulas Publications, 2003), 337; Κατερίνα Φουντεδάκη, Μαρία Γερασοπούλου, and Βασίλειος Μαρούδας, *Αστική Ιατρική Ευθύνη* [hereinafter: Katerina Fountedaki, Maria Gerasopoulou, and Vasileios Maroudas, *Civil Medical Liability*] (Athens: Nomiki Bibliothiki, 2023), 54, 202.

[38] For the treatment contract, which is specifically regulated in BGB, see among others: Deutsch and Spickhoff, *Medizinrecht*, no. 96 et seq.

which covers the entire course of medical care/treatment, from diagnosis to aftercare,[39] the physician has duties of treatment and information. Any breaches of duty by the physician can lead to liability for damages under §§ 630a, 280 I of the German Civil Code (hereinafter referred to as "BGB"). Breach of duty ("Pflichtverletzung") occurs when the physician's conduct is contrary to the standard of care ("Sorgfaltsmaßstab"), which in turn is determined objectively, according to § 630a II BGB,[40] which stipulates that: "Unless agreed otherwise, the treatment is to take place according to the generally recognised standards of medical care applying at the time of the treatment."[41] The physician bears subjective liability, under the general fault principle, for the breach of an objective standard of care, that of the medical standard. According to the established case law of the Federal Court of Justice (BGH), the medical standard specifies the appropriate conduct of the physician for the specific therapeutic situation and is determined by the objective circumstances, the rules of science and in particular, the rules of the physician's specialty, as well as by the findings of medical experience at the time the treatment is provided. It represents the current state of scientific knowledge and medical experience, that is required to achieve the specific therapeutic purpose, and which has been shown to be suitable for that purpose during trials.[42] Thus, the medical standard prescribes the manner in which the medical procedure is to be carried out, but at the same time, it also constitutes a measure in the examination the physician's liability, since, in view of § 630a II BGB, a breach of the medical standard implies a breach of the duty of care.[43]

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39 See: Christian Katzenmeier, in *Arztrecht*, ed. Adolf Laufs, Christian Katzenmeier and Volker Lipp (München: C.H. Beck, 2021), Cap. X no. 3 et seq. and 41 et seq.

40 See: Christoph Jansen, *Der Medizinische Standard. Begriff und Bestimmung ärztlicher Behandlungsstandards an der Schnittstelle von Medizin, Haftungsrecht und Sozialrecht* (Berlin, Heidelberg: Springer Verlag, 2019), 106 et seq.

41 "German Civil Code BGB," Bundesministerium der Justiz, accessed February 23, 2024, https://www.gesetze-im-internet.de/englisch_bgb/englisch_bgb.html#p3069.

42 See for instance: Federal Court of Justice [Bundesgerichtshof], Judgment of 22 December 2015, VI ZR 67/15 in *Neue Juristische Wochenschrift* 69, no. 10 (March 2016): 714. For the various definitions that have been proposed for the concept of medical standard, see: Jansen, *Medizinische Standard*, 199 et seq.

43 See: Dieter Hart, "Haftungsrecht und Standardbildung in der modernen Medizin: e–med und Probleme der Definition des Standards," *Medizinrecht* 34, no. 9 (October 2016): 671.

Similarly, in the event of a breach of the duty of care, the physician will also be liable in tort under § 823 I and II BGB. According to § 823 I BGB, anyone who unlawfully and culpably infringes the legal interests of another person is liable to provide compensation for the damage that occurred. Of particular importance in this context are the so-called duties of care ("Verkehrspflichten"), that require not to endanger someone more than is unavoidable.[44] It is thus well established that any medical error always constitutes a breach of the physician's duty of care in the sense above. In medical liability law, the physician's duties of care are identical to their corresponding contractual obligations, since contractual medical liability is essentially derived from the law of medical tort liability, as this has been developed in the context of case law.[45] In that sense, what has been said about the contractual liability of the physician and medical standards also applies here. Therefore, where the physician's conduct falls short of the medical standard applicable in the particular case, they are also liable under tort law.

3.1.2. Medical Liability as Subjective Liability – The Allocation of the Burden of Proof and the Patient's Evidentiary Difficulties

Regardless of its legal basis, i.e. whether it is contract law or tort law, the physician's liability for any breaches of duty is regarded as subjective liability under German law. The principle of fault is the rule here. This applies to both contractual (§ 276 I BGB),[46] and non–contractual liability (§ 823 I BGB).[47] The only difference between the two is that in contractual liability, according to § 280 I 2 BGB, the fault of the debtor is presumed. This means that it is not

For medical guidelines and the way the medical standard is determined in practice, see in detail: Jansen, *Medizinische Standard*, 16–7, 28, 204.

44 See in detail: Christian von Bar, *Verkehrspflichten: richterliche Gefahrsteuerungsgebote im deutschen Deliktsrecht* (Köln: Carl Heymanns Verlag, 1980). Specifically for the breach of the duty of care as a ground of liability of the physician due to medical error, see: Kern and Rehborn, *Handbuch des Arztrechts*, § 96 no. 17 et seq.; Jansen, *Medizinische Standard*, 49 et seq.

45 Katzenmeier, *Arztrecht*, Cap X no. 2 and XI no. 63.

46 Georg Caspers, *J. von Staudingers Kommentar zum Bürgerlichen Gesetzbuch: Staudinger BGB-Buch 2: Recht der Schuldverhältnisse: BGB §§ 255–304 (Leistungsstörungsrecht 1)*, rev. ed., eds. Georg Caspers et al. (Otto Schmidt/De Gruyter - de gruyter, 2019), § 276 no. 7 et seq.

47 See, among others: Volker Emmerich, *BGB–Schuldrecht Besonderer Teil*, 16th ed. (Heidelberg: C.F. Müller, 2022), § 20 no. 3 et seq.

the creditor who has to prove the fault of the debtor, but the debtor who has to prove the absence of fault on their part.[48] Thus, in medical liability and in so far as the specific provisions on the treatment contract do not contain a derogation from the general rules on contractual liability,[49] the physician is liable in the same way as any debtor, i.e. for intent and negligence. Moreover, given the objective definition of the standard of care in medical services, any breach of the physician's duty of care shall almost always constitute both unlawful and culpable conduct.[50]

Furthermore, in German law, following the general rule on the allocation of the burden of proof, the plaintiff bears the burden of proving the facts on which their action is based.[51] In medical liability cases this means that the patient bears the burden of proving the culpable breach of the duty of care (i.e. medical error as conduct falling short of the medical standard), the damage suffered, and the causal link between the culpable breach and the respective damage. Also, given the objectification of negligence, of which medical standards are also an expression,[52] the reversal of the burden of proof in the case of contractual liability does not seem to contribute anything to the patient's evidentiary assistance; with the exception of the cases of § 630h I BGB,[53] the patient continues to bear the burden of proving medical error even under § 280 I 2 BGB, since this provision covers only

48 For this provision, see: Daniel Ulber, *Erman BGB*, 17th ed., eds. Harm Peter Westetrmann, Barbara Grunewald, and Georg Maier-Reimer (Köln: Otto Schmidt Verlag, 2023), § 280 no. 115 et seq.

49 Deutsch and Spickhoff, *Medizinrecht*, no. 412. For fault liability in medical liability law, see: Kern and Rehborn, *Handbuch des Arztrechts*, § 92, no. 4 et seq.

50 See: Jansen, *Medizinische Standard*, 58, 71.

51 Although it is not explicitly stated in the ZPO or in any other legislative act, it is considered a fundamental rule on the allocation of the burden of proof with legislative force. See, among others: Hans-Jürgen Ahrens, *Der Beweis im Zivilprozess*, 1st ed. (Köln: Otto Schmidt Verlag, 2014), § 32 no. 32.

52 See: Karl Larenz, *Lehrbuch des Schuldrechts, Band I, Allgemeiner Teil*, 14th ed. (München: C.H. Beck, 1987), § 20 III; Erwin Deutsch, *Allgemeines Haftungsrecht*, 2nd ed. (Köln: Carl Heymanns Verlag, 1996): 259 et seq.; Adolf Laufs, "Deliktische Haftung ohne Verschulden? – Eine Skizze," in *Festschrift für Joachim Gernhuber zum 70. Geburtstag*, eds. Hermann Lange, Knut Wolfgang Nörr, and Harm Peter Westermann (Tübingen: J.C.B. Mohr P. Siebeck, 1993), 245, 248.

53 See: Lothar Jaeger, *Patientenrechtegesetz* (Karlsruhe: VVW, 2013), § 630h, no. 1 et seq.; Deutsch and Spickhoff, *Medizinrecht*, no. 795 et seq.

the internal aspect of negligence ("Verschulden"), which, however, is given in almost every case of externally negligent conduct ("Pflichtwidrigkeit") in the sense of a medical error, the burden of proof of which, however, remains with the patient.[54] It is therefore obvious that the patient, being generally uneducated in medical matters, is faced with serious evidentiary difficulties, hence with the consequent risk of having their claim rejected, as any *non-liquet* situation will always be to their detriment.[55] However, as was rightly pointed out, a general reversal of the burden of proof (i.e. the introduction of a general presumption of medical error) would be doctrinally impermissible. This is because the biological and physiological reactions of a human organism cannot be predicted with certainty, and therefore controlled, something that in turn means that any damage to the patient's body or health cannot always be within the physician's sphere of influence. Therefore, the mere occurrence of damage cannot justify a general presumption of a medical error[56].

3.2. Liability Regime under Greek Law

3.2.1. General Overview: Medical Liability and the Average Reasonably Prudent Physician – The Breach of the Rules of Medical Science

Similarly, under Greek Law, a physician who causes harm to a patient is liable both under contract and tort law. Thus, in the case of a treatment contract

54 Kern, *Handbuch des Arztrechts,* § 106 no. 16; Jansen, *Medizinische Standard*, 58, 71, mainly 102 et. seq; see also: Conrad Waldkirch, *Zufall und Zurechnung im Haftungsrecht* (Tübingen: Mohr Siebeck, 2018), 147.

55 Christoph Jansen and Christian Katzenmeier, "Beweismass, Beweislast und Haftung für den Verlust von Heilungschancen–Kausalitätsfragen im Arzthaftungsprozess in der Schweiz und in Deutschland," in *Das Zivilrecht und seine Durchsetzung. Festschrift für Professor Thomas Sutter-Somm*, eds. Roland Fankhauser et al. (Zürich: Schulthess, 2016), 285.

56 See: Gottfried Baumgärtel, "Die beweisrechtlichen Auswirkungen der vorgeschlagenen EG-Richtlinie zur Dienstleistungshaftung," *Juristen Zeitung* 47, no. 7 (April 1992): 322; Jansen and Katzenmeier, "Beweismass," 286. On the contrary, in cases where the patient's injury is the result of a fully controllable therapeutic risk, it is conceivable to provide for a presumption of medical malpractice in favor of the patient (see thus § 630h I BGB). Similarly, in cases of gross negligence ("grober Behandlungsfehler") it is perfectly justifiable and permissible to provide for a presumption of causality between the negligence and the resulting damage (630h V BGB) – for details on these provisions, which constitute a codification of established case law of the BGH, see, among others: Deutsch and Spickhoff, *Medizinrecht*, no. 795 et seq. and 374 et. seq. respectively.

between the physician and the patient, the Greek courts apply in parallel the provisions on tort [Article 914 et seq. of the Greek Civil Code (hereinafter referred to as Greek CC)] with the provisions applicable to service contracts (in particular, Article 652 Greek CC).[57] In contrast to German law, the treatment contract in Greek law is not specifically regulated. However, the contractual relationship between the physician and the patient constitutes a service contract. Thus, the contractual liability for medical malpractice (in the sense of a medical error) is assessed under Article 652 Greek CC in conjunction with the general liability provisions of the law of obligations. The provision of Article 652 paragraph 2 Greek CC is a specification of that of Article 330 section b Greek CC[58] focusing on an objective standard of care, the non-observance of which entails the physician's liability.[59]

The focus, however, is placed on medical error as a prerequisite for establishing the physician's liability in tort, since, contrary to German law, it is only on this basis that the injured party can claim compensation for non-material/moral damage or emotional distress under Article 932 Greek CC.[60] Under the general provision regarding torts, expressed in Article 914 Greek CC: "A person who unlawfully and through his fault has caused prejudice to another shall be liable for compensation."[61] Medical error that causes damage to the patient's body or health is consistently recognized as a case of application of Article 914 Greek CC. Due care is determined objectively: according to the established case law of the Greek courts, a breach of the duty of medical care occurs with the breach of the rules of medical science and experience and/or of the general duty of care and safety, that the average

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57 Κατερίνα Φουντεδάκη, *Παραδόσεις Αστικής Ιατρικής Ευθύνης* [hereinafter: Katerina Fountedaki, *Lessons of Civil Medical Liability*] (Athens: Nomiki Bibliothiki, 2018), 47; Fountedaki, Gerasopoulou and Maroudas, *Civil Medical Liability*, 187.

58 Μιχαήλ Π. Σταθόπουλος, *Γενικό Ενοχικό Δίκαιο*, 5th ed. [hereinafter: Michail P. Stathopoulos, *General Law of Obligations*, 5th ed.] (Athens: Sakkoulas Publications, 2018), 652. It is worth noting that the provision of Article 330(b) of the Greek CC is identical to that of § 276 II BGB.

59 For that specifically in medical liability the standard of care of Article 652 paragraph 2 Greek CC must be defined in an objective manner. See: Fountedaki, *Civil Medical Liability*, 338–9.

60 Fountedaki, Gerasopoulou and Maroudas, *Civil Medical Liability*, 188.

61 As translated by Eugenia Dacoronia, in "Tort Law in Greece. The State of Art," in *Studia in Honorem Pelayia Yessiou–Faltsi*, eds. Nikolaos Th. Nikas et al. (Athens: Sakkoulas Publications, 2007), 57.

reasonably prudent physician of the relative specialty must demonstrate.[62] At the heart of due care thus lies the average reasonably prudent physician (*bonus medicus*) and the rules of medical science (*leges artis*).[63] Alongside this general view of due care, the Code of Medical Ethics (Kodikas Iatrikis Deontologias – Law 3418/2005), sets out criteria for the specification of the physician's duty of care, establishing specific legal (and not just ethical) obligations, the breach of which constitutes a breach of the duty of due care.[64] Hence, according to Article 3 paragraph 3 of the Code, the physician is obliged to perform any medical procedure within the framework of the generally accepted rules[65] and methods of medical science, as formulated on the basis of the results of applied modern scientific research. From the perspective of Article 3, which even refers to evidence-based medicine (see paragraph 2c), the criterion of the average reasonably prudent physician seems to lose its static character, approaching to a certain extent the concept of medical standards as explained above.[66] In any case, a physician, whose conduct falls short of that required by the results of applied modern scientific research (a concept close to that of the medical standard) is liable for compensation if this conduct causes harm to the patient.

3.2.2. Medical Liability as Subjective Liability – The Allocation of the Burden of Proof and Article 8 of Greek Law 2251/1994

As in German law, medical liability in Greek law is a form of subjective liability. Given the lack of explicit regulation, it is covered by the general provisions on contractual and tort liability, which establish the principle of fault.[67] Their only difference is that contractual liability is regulated as

62 See: Supreme Civil and Criminal Court of Greece (Άρειος Πάγος), Judgment of 4 June 2007, no. 1227/2007, in the home page of the Supreme Civil and Criminal Court of Greece, accessed February 9, 2020, https://www.areiospagos.gr/nomologia/apofaseis_DISPLAY.asp?cd=j5ZUkHPjtZqv6ohr6jRR0JbPAgT03z&apof=1227_2007&info=%D0%CF%CB%C9%D4%C9%CA%C5%D3%20-%20%20%C12.

63 Fountedaki, *Civil Medical Liability*, 351 et seq.; Fountedaki, Gerasopoulou and Maroudas, *Civil Medical Liability*, 206 et seq.

64 See: Fountedaki, *Lessons*, 17–8; Fountedaki, Gerasopoulou and Maroudas, *Civil Medical Liability*, 57.

65 See also: Article 10 paragraph 1(a) of the Code.

66 See also: Fountedaki, Gerasopoulou and Maroudas, *Civil Medical Liability*, 210, 223.

67 For fault liability in Greek law, see, among others: Stathopoulos, *General Law of Obligations*, 389; Παναγιώτης Κορνηλάκης, *Ειδικό Ενοχικό Δίκαιο*, 3rd ed. [Panagiotis Kornilakis, *Special Part of the Law of Obligations*] (Athens: Sakkoulas Publications, 2023), 1588.

liability for presumed fault (Article 336 Greek CC), in the sense mentioned above, i.e. that the debtor bears the burden of proving the absence of fault on their part.[68] The physician is therefore liable for intent or negligence, irrespective of the legal basis of their liability, i.e. whether it is contractual or in tort. Moreover, given the objective conception of the duty of due care, as stated above, a medical error will almost always constitute a conduct both unlawful and culpable.[69]

However, in cases of liability for medical malpractice, in addition to the general provisions, a special provision of the Consumer Protection Law (Greek Law 2251/1994) applies, that is of considerable importance: article 8 of the law, which regulates the liability of the supplier of services and which, in its basic content, implements the corresponding EU Proposal for a Directive of 1990.[70] According to the most correct approach, this provision does not introduce independent legal grounds for liability,[71] but merely regulates in a specific way certain issues of (the general) tort liability of the supplier of services.[72] In addition to providing certain criteria for establishing the supplier's unlawful and culpable conduct, it also contains a specific regulation on the allocation of the burden of proof, that deviates from the generally applicable provisions of the Greek Code of Civil Procedure (hereinafter referred to as Greek CCP). This point is of particular importance and requires attention.

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68 For contractual liability as liability for presumed fault, see: Stathopoulos, *General Law of Obligations*, 1283.

69 Fountedaki, *Civil Medical Liability*, 335 et seq.; Fountedaki, Gerasopoulou and Maroudas, *Civil Medical Liability*, 201. On the more specific problem regarding medical error as a form of unlawful conduct as well as its relation to the objectification of negligence, see: Fountedaki, Gerasopoulou and Maroudas, *Civil Medical Liability*, 189 et seq. and 197 et seq. respectively.

70 See: (EC) Proposal for a Council Directive on the liability of suppliers of services [COM(90) 482 final — SYN 308], 9 November 1990, accessed February 20, 2024, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:51990PC0482. However, the Proposal was heavily criticized, especially with regard to civil medical liability, with the result that the whole project of unifying the laws in the field of liability of the supplier of services was abandoned a few years later (1994). See, among others: Baumgärtel, "Die beweisrechtlichen Auswirkungen," 321 et seq.

71 This is, however, the prevailing view in Greek law. Among others see: Stathopoulos, *General Law of Obligations*, 989 fn. 100.

72 See: Fountedaki, *Civil Medical Liability*, 100–2, where this view is first articulated.

According to the general rule on the allocation of the burden of proof of Article 338 paragraph 1 Greek CCP, each party is subject to the burden of proving the evidence supporting its claims.[73] Thus, the plaintiff in tort is required to prove the wrongful and culpable conduct of the defendant, the damage suffered, and the causal link between the two. Therefore, under the general rule on the allocation of the burden of proof of Article 338 paragraph 1 Greek CC, the patient would be obliged to prove a medical error on the part of the physician (i.e. their unlawful and culpable conduct), the damage sustained, as well as the causal link between the two. Moreover, the rule of Article 336(a) Greek CC on presumed fault in contractual liability would not be of assistance to the patient, since in medical liability it would by definition have the limited content of a reversal of the burden of proof regarding fault, the existence of which, however, would be given by the mere objective breach of the duty of care, whose burden of proof the patient would continue to bear.[74] Thus, the patient would be relieved of the burden of proving an element (fault), the existence of which would necessarily be inferred from the objective deficiency of the medical service, the burden of proof of which they would still have to bear.

Contrary to that general rule, Article 8 sets out a completely different allocation of the burden of proving the conditions of liability. This is where its practical importance for medical liability lies; it is not the injured party who has to prove unlawful and culpable conduct of the supplier (i.e. the physician), but instead, it is the latter who bears the burden of proving the absence of such conduct. In the context of medical liability, this rule has the effect of introducing a general presumption of medical error to the detriment of the physician. Similarly, it is not the injured party who must prove the existence of a causal link between the supplier's error and the damage suffered, but rather the latter who bears the burden of proving the absence of such a causal link. In medical liability, this means the introduction of a presumption of causality between the (presumed) medical error

73 See in more detail: Pelayia Yessiou–Faltsi, *Civil Procedure in Hellas*, 2nd rev. ed. (Athens: Sakkoulas Publications, 2022), 378 et seq.

74 Details on the meaning of the presumption of the debtor's fault in contractual liability and medical liability and the relationship of the general provisions on contractual liability with article 8 of Law 2251/1994, see: Fountedaki, *Civil Medical Liability*, 103 et seq. and 139 et seq.; Fountedaki, Gerasopoulou and Maroudas, *Civil Medical Liability*, 70 et seq. and 290.

and the patient's harm.[75] Thus, the patient bears only the burden of proving the provision of the medical service, the damage suffered, and the causal link between the two (Article 8 paragraph 3). The combination of these two presumptions ultimately means that by the mere damaging effect of a medical procedure it is presumed both that there was a medical error and that this error caused the damage sustained.[76] The provision of Article 8 was rightly criticized as doctrinally inappropriate for regulating medical liability,[77] since the allocation of the burden of proof imposed by it results in the disguised conversion of medical liability into strict liability, at least in cases where the physician is unable to prove the absence of error on their part and/or causality between that error and the damage sustained. However, it cannot be denied that in practice it is an important aid to the patient,[78] who, in a (pure) subjective liability regime, would risk bearing the negative effects of a *non-liquet* situation.

4. Medical Liability for Damage Caused by the Use of AI: A Comparative Analysis

What is the significance of the above general regulations of medical liability under German and Greek law to the use of autonomous systems in the provision of medical services? Also, to what extent and in what way does the current legal framework cover the damage caused by the use of AI systems in medicine, if it does so at all? The following analysis focuses on this issue, in the hope of providing some answers. It should be noted that, due to the proximity between Greek and German medical liability law as described above, the analysis is largely uniform, however, where differentiations need to be made (specifically with regard to the burden of proof), this is explicitly pointed out. Moreover, since on the one hand, *lex artis* and medical

75 For the presumption of medical error and the presumption of causation as the basic content of Article 8 in the context of medical liability, see: Fountedaki, *Civil Medical Liability*, 103 et seq.; Fountedaki, *Lessons*, 116 et seq.; Fountedaki, Gerasopoulou, and Maroudas, *Civil Medical Liability*, 289 et seq.

76 Ibid., 291.

77 For a criticism at a doctrinal lever, see: Fountedaki, *Civil Medical Liability*, 145 et seq.; compare also: Fountedaki, Gerasopoulou and Maroudas, *Civil Medical Liability*, 298 et seq.

78 See, however: Fountedaki, *Lessons*, 125 et seq., who observes that in practice Greek courts do not apply the provision in its true sense, with the result that a *non-liquet* situation is not always to the detriment of the physician.

standards do not differ significantly, and on the other hand, medical standards for the use of AI systems have not yet been developed,[79] with the result that German law also resorts to the criterion of the average reasonably prudent physician (*bonus medicus*),[80] the uniform examination of the relevant issues does not seem to raise any doctrinal problems whatsoever.

4.1. The Permissibility of the Use of AI Systems in the Provision of Medical Services – The Use of Autonomous Systems as a Breach of Duty *per se*

The first and main question is whether the use of autonomous systems is in any way permissible in the context of medical practice. Indeed, it was argued that, since autonomous systems are not subject to full human control, due to the lack of transparency and predictability of their operations, their use would entail incalculable risks, thus constituting a breach of duty *per se*.[81] Such a view could of course in no way be accepted.[82] Apart from being based on an incorrect premise, as autonomous systems are perceived as safer than systems under human control,[83] duties of care do not generally extend to the point of guaranteeing absolute safety.[84] If this were the case, especially in the context of medical liability, it would have the effect of making virtually any medical procedure impossible, since no physician would ever be able to guarantee absolute safety for anything.[85] But just as a physician cannot (and is not required to) guarantee absolute safety when using a human-controlled machine, they cannot be required to guarantee an error-free operation of the autonomous system. Considering the use of autonomous systems as a breach of duty would mean establishing the autonomy of the

79 Zech and Hünefeld, "Einsatz," 3.

80 For relevant case–law regarding the criterion of the average reasonably prudent physician, see: Hans-Peter Greiner, *Arzthaftpflichtrecht*, 8th ed., eds. Karlmann Geiß and Hans-Peter Greiner (München: C.H. Beck, 2022), Cap. B, no. 2 et seq.

81 See: Zech, "Entscheidungen digitaler autonomer Systeme," 55; Teubner, "Digitale Rechtssubjekte?," 185 et seq.

82 Opposed to this view: Jan Eichelberger, "Arzthaftung", in *Künstliche Intelligenz – Recht und Praxis automatisierter und autonomer Systeme*, eds. Kuuya J. Chibagunza, Christian Kuß, and Hans Steege (Baden–Baden: Nomos, 2022), § 4 I no. 12; Wagner, "Verantwortlichkeit," 727; Christian Katzenmeier, "KI in der Medizin – Haftungsfragen," *Medizinrecht* 39, no. 10 (October 2021): 860 et seq.; Schmidt, "Die Auswirkungen," 344.

83 Geistfeld et al., *Civil Liability*, 37.

84 Wagner, "Verantwortlichkeit," 727.

85 See: Katzenmeier, "Haftung für Schäden," 78–9.

system as a reason for the physician's liability; this, however, would be contrary to the fault principle, for it would have the effect of transforming the physician's liability into a risk-based strict liability.[86]

4.2. The Use of AI Systems in the Light of the Criteria for Establishing Medical Liability – Autonomous Systems as Novel Methods

However, the question of the permissibility of the use of AI technology could also be raised on a different basis. Given that autonomous systems constitute a novelty for medical practice, the question arises whether and to what extent they meet the criteria of due medical care under German and Greek law, as discussed above.

As mentioned, under German law, medical liability arises when the physician's conduct fails to meet medical standards. The medical standard is clearly a normative concept as it indicates the required medical conduct in a specific case; at the same time, however, it is a dynamic and flexible concept, since it allows for the convergence of legal assessments of medical malpractice with the constant developments in the field of medical science.[87] In this sense, § 630a II BGB allows for the use of new therapeutic methods, irrespective of the fact that they have not yet been widely applied.[88] However, this is possible only under certain conditions. A physician who wishes to use a new method must first carry out a risk assessment for this new method and the methods indicated by the current standards and use it only if it offers significant advantages for the patient (correspondingly entailing significantly fewer risks).[89] In the case of autonomous systems that can process a huge amount of data and thus make personalized treatment recommendations for the individual patient, the advantages for the latter are considerably greater, since the treatment decision is based on processing much more data than a human being could ever take into

86 Ibid.

87 See, among others: Jansen, *Medizinische Standard*, 48–9.

88 Thomas Gutmann, ed., in *J. von Staudingers Kommentar zum Bürgerlichen Gesetzbuch: Staudinger BGB - Buch 2: Recht der Schuldverhältnisse: §§ 630a-630h (Behandlungsvertrag)*, rev. ed. (Otto Schmidt/De Gruyter - de gruyter, 2021), § 630a no. 146.

89 See: Deutsch and Spickhoff, *Medizinrecht*, no. 339; in detail see: Lena Schneider, *Neue Behandlungsmethoden im Arzthaftungsrecht. Behandlungsfehler-Aufklärungsfehler-Versicherung* (Heidelberg: Springer, 2010), 25 et seq., especially 119 et seq.

account.[90] A more personalized treatment of the patient, however, always presents more advantages, and correspondingly fewer risks, for the patient than one based on evidence-based medicine.[91] Therefore, to the extent that an autonomous system presents more advantages for the patient, provided that it is a certified medical device according to the provisions of Regulation (EU) 2017/745 on medical devices,[92] it is clear that it can be used in the context of medical practice as the above cost-benefit analysis will most probably prove it to be beneficial for the patient.[93] The physician, of course, is a mere user and may not be in a position to know whether the system has been properly manufactured, programmed, or trained. However, their application in medical practice cannot be ruled out in advance only because of that. Yet, if the physician has evidence of a possible malfunction of the system, its use in the course of the treatment shall always constitute a breach of duty.[94]

It is similar in the context of Greek law. First of all, the use of therapeutic methods that are not scientifically documented is prohibited (Article 3 paragraph 3 section b of the Code of Medical Ethics), as well as that of new diagnostic or therapeutic methods for which there is no strong scientific evidence that their use or application will increase the chances of survival or restoration of the patient's health and that the benefit will seriously outweigh the risk of adverse effects (Article 25 paragraph 1 Code of Moral Ethics). However, apart from the fact that self-learning algorithms are not exactly a diagnostic/therapeutic method, but rather a specific way of processing knowledge,[95] the criterion of the average reasonably prudent physician, which, as highlighted above, is not so different from that of medical standards, appears to provide fertile ground for the smooth integration of the use of artificial intelligence into medical practice, at least in the way

90 Schmidt, "Die Auswirkungen," 345.

91 See also: Anna Maria Ernst, *Rechtsfragen der Systemmedizin* (Berlin: Springer Verlag, 2020), 138 et seq.

92 On this aspect of the issue see: Katrin Helle, "Intelligente Medizinprodukte: Ist der geltende Rechtsrahmen noch aktuell?," *Medizinrecht* 38, no. 12 (December 2020): 993 et seq.

93 See: Zech and Hünefeld, "Einsatz von KI," 4, who link the use of AI with therapy freedom ("freie Methodenwahl").

94 Helle, "Intelligente Medizinprodukte," 998; Schmidt, "Die Auswirkungen," 345.

95 Schmidt, "Die Auswirkungen," 346.

this criterion is specified by Article 3 of the Code of Medical Ethics.[96] Indeed, a systematic-teleological interpretation of the above articles which has as its reference point the best interest of the specific patient[97] (cf. Article 3 paragraph 3 of the Code, that refers to the choice of a method that is significantly superior to another for the patient in question), can only lead to the acceptance of the position that the use of artificial intelligence in medical practice in general does not constitute a breach of due medical care. To the contrary, given that, as demonstrated above, it is in principle a safer and more effective option for the patient, it has to be recognized as a permissible method. The opposite view works to the detriment of the patient. However, the choice rests with the patient, provided they have been adequately informed beforehand.[98] Here too, nevertheless, the final decision for or against the use of autonomous systems must be made by the physician based on a cost-benefit analysis. Of course, both in German and Greek law, risk assessments cannot be carried out *in abstracto*, but must be related to the particular autonomous system and the particular patient.

4.3. Duties of Medical Care When Using Autonomous Systems

The use of AI systems in the provision of medical services, although permissible, nevertheless entails certain obligations on the part of the physician/hospital to ensure that it is done in accordance with the required medical care. As in the case of any medical devices,[99] high safety and control requirements apply to the use of autonomous systems.[100] The physician is therefore required to be familiar with the basic functions of the AI system used[101],

96 In particular, the reference in paragraph 3 of the article to the physician's right to choose a method of treatment, which they consider to be significantly superior to another for the specific patient, based on the modern rules of medical science.

97 For the patient's best interests as the decisive criterion for determining the medical due care, see: Fountedaki, *Civil Medical Liability*, 367 et seq.; Fountedaki, Gerasopoulou and Maroudas, *Civil Medical Liability*, 214–5, 224–5.

98 See also for German law: Katzenmeier, "Haftung für Schäden," 80.

99 See: Schmidt, "Die Auswirkungen," 347, with further citations on BGH case law.

100 Katzenmeier, "Haftung für Schäden," 78. Zech and Hünefeld, "Einsatz von KI," 4.

101 Zech and Hünefeld, "Einsatz von KI," 4. See also the physician's lifelong learning duty to keep up to date with developments in medical science, Article 10 paragraph 1 of the Greek Code of Medical Ethics. For the same duties in German law, see: Kern and Rehborn, in *Handbuch des Arztrechts*, § 15 no. 22, § 96 no. 27 et seq.

with the way it works, as well as with the information related to its database.[102] The latter is very important, since, as stated above, even self-learning algorithms function only with the data made available to them, and therefore any errors in the database will necessarily lead to incorrect results. Thus, the physician must ensure that the system is up to date, as well as critically evaluate its results against the background of current medical developments. They are also obliged to maintain it regularly and if they cannot do it themselves, the task should be entrusted to experts. Maintenance in the case of software systems means the immediate installation of current updates, patches, bug fixes, etc.[103] Furthermore, they must oversee their proper operation on a regular basis.[104] This duty applies to medical devices in general and, at least for the time being must also apply to autonomous systems in medicine. This is because, at present, these systems perform an auxiliary role. The physician is still the central figure in making diagnostic and therapeutic decisions, something that justifiably means that sufficient control of the (pre)decision made by the systems is required on their part.[105]

In any case, irrespective of the physician's specific duties, which remain to be specified either in the context of case law or through the AI Act,[106] their general duty to use medical devices in such a way that any damage is prevented to the extent possible is intensified considerably when using AI systems, precisely due to the autonomy risk[107]: that is, namely, not because autonomous systems present an increased risk *per se*, but because it cannot be ruled out that they may have come into contact with human error and thus produce incorrect results. As has been aptly observed, the best way to

102 Schmidt, "Die Auswirkungen," 347. See also: Katzenmeier, "Haftung für Schäden," 78.

103 Schmidt, "Die Auswirkungen," 347.

104 Katzenmeier, "Haftung für Schäden," 78.

105 One may reasonably ask, however, whether and to what extent a physician can practically meet such an obligation, since, as discussed above, the action of autonomous systems *ex-ante* appears to be limitedly predictable and *ex-post* limitedly explainable. As rightly observed, the limited explainability of the autonomous system's activity may in fact constitute a limit, which, in relation to due medical care, could imply a limitation of what may be required of the average reasonably prudent physician, (see: Zech and Hünefeld, "Einsatz von KI," 4.)

106 See: Section 3 of Chapter III of the "AI–Act". However, it should be noted that the "AI–Act" has no civil liability regulations.

107 Spindler, "Medizin und IT," 588; Katzenmeier, "Haftung für Schäden," 78; Eichelberger, in *Künstliche Intelligenz*, § 4 I no. 41.

manage autonomy risk is by ensuring the appropriate formulation of the duties of care of the manufacturer, programmer, user, etc.[108] The question that arises, however, is how the patient can prove the breach of duty of care by the physician/hospital, and even more so the causal link between this breach and the incorrect output of the system, as well as that between the output and the damage sustained. The "black-box effect" seems to raise insurmountable evidentiary difficulties, to the point where the strength of the fault principle is tested, at least so long as the classic rule on the allocation of the burden of proof applies. Once again, nevertheless, we are confronted with a problem that must in principle be dealt with by the law of evidence.

4.4. The Physician's Liability from the Use of Autonomous Systems

If the physician breaches any of the duties outlined above, we are faced with a medical error. If this breach leads to patient injury, under both German and Greek law, given the general outlines presented above, the physician shall be liable for damages. The use of autonomous systems in medicine seems, thus, to induce a transition, or rather a transformation of the traditional concept of medical error into a program application error ("Programmanwendungsfehler").[109] Moreover, since no standards have yet been developed in relation to the use of self-learning systems, the criterion of the average reasonably prudent physician becomes of particular importance in this respect for German law as well.[110] Therefore, both in Greek and German law a physician who demonstrates such conduct in the use of autonomous systems that falls short of that which the average reasonable physician of the relevant specialty would be expected to display in a similar case is considered to have committed a medical error. However abstract this formulation may seem, in the absence of specific standards it takes on particular significance in cases of medical liability.

108 See: Digitaler Neustart, *Haftungsfragen*, 44.
109 Hart, "Haftungsrecht und Standardbildung," 675.
110 See: Zech and Hünefeld, "Einsatz von KI," 3.

4.4.1. Similarities between German and Greek Law: The Fault Principle and Autonomy Risk –Evidentiary Difficulties of the Patient as the Real Problem in Question

The link between medical liability and the breach of a specific duty of care around the use/maintenance etc. of the autonomous system follows from the very nature of medical liability as subjective liability. Therefore, errors that are theoretically linked to the autonomous activity of the system are not attributable to the physician/hospital and are hence regarded as accidental damages,[111] with the result that the patient is liable for them on the basis of the "casum sentit dominus" principle.[112] The fault principle, in the form of objectified negligence, means that the physician is liable only for breaches of the above-mentioned duty of care, i.e. for errors in the system which the average reasonably prudent physician should have foreseen and therefore avoided. Accordingly, it is only by proving such an error that the patient can be awarded damages. As has been pointed out, in this sense, we are faced with a liability gap.[113] The various theoretical arguments proposed in the context of German theory to fill this gap with tools of the applicable contract and/or tort law (e.g. arguments by analogy based on the provisions on vicarious liability or tort liability for animals) are not convincing and, as rightly observed, cannot be defended doctrinally.[114] Autonomous systems do not, of course, operate in a legal vacuum, but are subject to current regulations; they are therefore governed by the fault principle, which, seems, *prima facie*, to be insufficient for effectively regulating the autonomy risk at a theoretical level.

A closer examination of the issue, however, reveals that the real question that needs to be asked is to what extent we are dealing with a "liability gap" (i.e. with the inadequacy of the fault principle), not in theory, but

111 See: Sophie Burchardi, "Risikotragung für KI-Systeme–Zur Zweckmäßigkeit einer europäischen Betreiberhaftung," *Europäische Zeitschrift für Wirtschaftsrecht* 33, no. 15 (August 2022): 686; Georg Borges, "Haftung für KI-Systeme — Konzepte und Adressaten der Haftung," *Computer und Recht* 12, no. 9 (September 2022): 554.

112 See: Katzenmeier, "Haftung für Schäden," 80.

113 See, among others: Teubner, "Digitale Rechtssubjekte?," 157 et seq., 185 et seq.

114 For these arguments, which have been exhaustively analyzed in the context of legal theory in recent years and for this reason it is considered unnecessary to be presented here, see, among others: Wagner, "Verantwortlichkeit," 729 et seq.; specifically in the context of medical liability see: Katzenmeier, "Haftung für Schäden," 80 et seq. and 82 et seq.

in practice, especially a gap of such a nature that could justify the reform of substantive law with the tools of risk-based strict liability. As has been pointed out already, AI systems do not present a risk in themselves, simply because they are autonomous. In this sense, the theoretical problem of attributing autonomous errors does not seem to justify a substantive law reform to the detriment of the fault principle. On the contrary, the fault principle, in its objectified form (see objectified negligence) appears to adequately protect the patient, at least at a substantive level, by imposing increased duties of care on the physician in relation to the use of AI systems. What is of particular importance, however, is the insurmountable evidentiary difficulties with which the patient is confronted, when it comes to proving the breach of one of these duties. The fault principle is inadequate precisely to the extent that it places the burden of proving hard-to-prove evidence on the injured patient. The "black-box effect" does not make autonomous systems dangerous, however, it makes the injured patient unable to identify the cause of their injury and thus deprives them of the chance to make any effective claim against the physician.

4.4.2. The Allocation of the Burden of Proof as a Critical Factor in Determining Medical Liability Arising from the Use of Autonomous Systems – Differences between German and Greek Law

In German law, the patient who sues the physician/hospital for compensation bears the burden of proving a medical error, the damage suffered, and the causal link between the error and the damage. In the context of damage arising from the use of an autonomous system, this means that they must, first of all, prove the breach of a duty of care related to the system, its causal link with the incorrect output, as well as the link between the latter with the damage sustained. Thus, the patient is required to prove not only the specific technical error but also that the average reasonably prudent physician should have been able to foresee and thus prevent that error.

However, just as the physician cannot perfectly foresee the behavior of the system, so *a fortiori* the patient, who, unlike them, does not know anything about the system, will not be able to explain it, let alone link it to the breach of a specific duty of care on their part, as required by the fault principle. Moreover, taking into account the inherent evidentiary difficulties the patient faces in relation to medical matters, in case they are unable to prove (a) the breach of a specific duty of care by the physician and

(b) its causal link with the damage suffered, they are the ones who must bear the financial consequences of the damage caused by the physician/hospital.[115] The allocation of the burden of proof on the basis of the general rule has, in this case, the peculiar effect of a "shifting" liability (in the sense of a "Haftungsverlagerung") to the detriment of the patient.[116] Moreover, the provisions of § 630h I BGB[117] cannot be applied in the patient's favor. Unlike most technical devices, whose operation falls within the concept of fully controllable risk,[118] autonomous systems are beyond the full control of the user.[119] This provision cannot be applied even through teleological reduction,[120] for its letter is perfectly clear: it refers to a "voll beherrschbares Behandlungsrisiko."[121] Any other approach constitutes an impermissible *contra legem* interpretation. On the contrary, there seem to be grounds for the application of § 630h V BGB,[122] since errors in the use/maintenance of the autonomous system can and should be considered medical errors. Thus, in the case where a physician fails, for example, to install a very important update to the AI software, it seems to be possible to argue that this omission is linked, for example, to an incorrect diagnosis to the detriment of the patient (rebuttable presumption of causality).

It is clear that the provisions of German law appear unfair, at least in terms of assessments related to the spheres of influence of the parties

115 On how the burden of proof works in *non-liquet* cases, see, among others: Hanns Prütting, *Münchener Kommentar zur Zivilprozessordnung: ZPO, Band 1: §§ 1–354*, 6th ed., eds. Wolfgang Krüger and Thomas Rauscher (München: C.H. Beck, 2020), § 286 no. 107 et seq. Furthermore, on the practical significance of the burden of proof in cases of tort liability, see, among others: Ernst Karner, "The Function of the Burden of Proof in Tort Law," in *European Tort Law 2008*, eds. Helmut Koziol and Barbara C. Steininger (Vienna: Springer Wien New York, 2009), 68 et seq.

116 On the rules on the allocation of the burden of proof as a means of "shifting" liability from one party to another, see: Hans Stoll, "Haftungsverlagerung durch beweisrechtliche Mittel," *Archiv für die civilistische Praxis* 176, no. 2/3 (1976): 145 et seq.

117 Presumption of a medical error due to fully manageable general treatment risk ("voll beherrschbares Behandlungsrisiko"). See herein fn. 57.

118 Deutsch and Spickhoff, *Medizinrecht*, no. 796.

119 Oliver Brand, "Haftung und Versicherung beim Einsatz von Robotik in Medizin und Pflege," *Medizinrecht* 37, no. 12 (December 2019): 950; Spindler, "Medizin und IT," 593.

120 See: Brand, "Haftung und Versicherung," 950.

121 Schmidt, "Die Auswirkungen," 351.

122 See among others: Deutsch and Spickhoff, *Medizinrecht*, no. 374 et seq.

("Sphärenbetrachtungen"). This is because they entail a distribution of risk at the expense of a person who has no control or influence over the autonomous system. On the contrary, the physician/hospital is able to influence its operation (to a certain extent), for example, by employing qualified staff to control, maintain, and/or monitor it. Be that as it may, it seems unfair that the patient should bear the adverse consequences of a *non-liquet* situation when the physician/hospital derives financial and professional benefits from the use of the system ("Vorteilsziehung").[123] We are therefore faced with the realization that legislative interventions in the law of evidence for the benefit of the patient seem imperative at this point.

In contrast to German law, the situation is different in the context of Greek law. Indeed, as demonstrated above, it is not the patient who bears the burden of proving the medical error and its causal link to the harm suffered, but the physician who must prove (a) that they did not commit a medical error, and (b) that there is no causal link between the patient's harm and the presumed error. The patient therefore has two very powerful weapons in their evidentiary arsenal; namely, a presumption of medical error and a presumption of causation. In the context of injury sustained from the use of an autonomous system, this means that it is presumed that the physician has committed an error in connection with the use/maintenance of the system, as well as that this error is causally related to the patient's injury. The presumption of error has precisely the meaning that in case of doubt, the physician has breached a duty of care, whereas the presumption of causation means that in case of doubt the patient's injury is due to that (presumed) breach of the duty of care. It is, therefore, the physician/hospital that bears the adverse consequences of autonomy risk, since they are the ones who are faced with the evidentiary difficulties arising from the operation of the system, i.e. they have to prove that the patient's injury is not due to an error in relation to the use/maintenance etc. thereof.

However, it seems that the physician may find it easier, or rather less difficult, to meet this burden of proof than the patient in the opposite case (see German law). This is because it is sufficient for them to prove that they

[123] See: Jürgen Oechsler, "Die Haftungsverantwortung für selbstlernende KI-Systeme," *Neue Juristische Wochenschrift* 75, no. 38 (September 2022): 2713, 2714 et seq.

have complied with the duties of care inherent in the use and maintenance of the AI system and, accordingly, that the patient's injury was caused by an error in the system, which even the average reasonably prudent physician of the respective specialty could not have foreseen and prevented. With all the difficulties that the limited explainability of the system's behavior ("black-box effect") entails for this proof, it seems to constitute an allocation of the burden of proof that is fairer than that imposed by the general principle in German law. This is because the autonomous system is within the sphere of influence of the physician/hospital,[124] and certainly to a much greater extent than that of the patient, who will, in all likelihood, not know anything about it.[125] The "black-box effect" certainly affects the physician/hospital, but it affects the patient much more, as the latter does not have, nor is required to have, the slightest insight into the respective technical matters. Thus, it can in no way be used as an argument for allocating the burden of proof in favor of the physician, since, in most cases, the patient will have a much greater information deficit than they. If the "black-box effect" is to be used as an argument in favor of anyone, at least in matters of burden of proof, this can be no one else apart from the patient. For all the lack of absolute transparency around the operation of the autonomous system, the physician is demonstrably closer to it than the patient, and in any case, has access to much more information than the latter. After all, the physician/hospital derives economic and operational benefits from the use of the system, so it only seems fair, even from this point of view, that they should bear the respective burden of proof.

Contrary, therefore, to what is the case in traditional medical liability, where the provision of Article 8 has been rightly criticized as doctrinally inappropriate to regulate the allocation of the burden of proof, the opposite seems true in cases where AI systems are used. The provision implies a balancing solution that takes into account the interests of both the patient and the physician/hospital and, in any case, in the dilemma of who should bear

124 At least to some extent.

125 See also: Brand, "Haftung und Versicherung," 950, who proposes a teleological reduction/corrective interpretation of § 630h I BGB in order to include autonomous systems in the presumption of fault, and this on the basis that the autonomous system belongs to the organizational domain of the physician/hospital.

the adverse consequences of a *non-liquet* situation due to autonomy risk, chooses, even when unknowingly,[126] the latter.

The physician/hospital is the one who has chosen to apply an autonomous system in their organization; they are the ones who have put it into operation to serve their professional interests, and they decide on the place, time, and manner of its use.[127] They are also demonstrably closer to it and they, upon the correct observance of the relevant duties of care, can to a sufficient extent prevent or deal with the occurrence of any errors. Accordingly, they are in the position to employ qualified personnel to ensure that the system is used in the best possible way. The bottom line is that the physician is in a much more advantageous position than the patient and it is only fair that they should bear the burden of proof in relation to autonomy risk.[128] Greek medical law thus appears, even if unwittingly, to be better prepared to welcome the use of autonomous systems in medical practice in matters of civil liability.[129]

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126 Basically, literally without the knowledge of the legislator, in view of the fact that this is a 1994 provision.

127 See: Zech, "Entscheidungen digitaler autonomer Systeme," 88.

128 It is also worth noting that a similar solution (presumption of fault and presumption of causality) for damages caused by the use of artificial intelligence in general, was proposed by the European Commission in its White Paper on Artificial Intelligence (See reference in Wagner, "Verantwortlichkeit," 736–7 with further references), as well as by the European Parliament in the context of the European Parliament resolution of 20 October 2020 with recommendations to the Commission on a civil liability regime for artificial intelligence (2020/2014(INL)), (see Article 4 and 8 of the Proposal in https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52020IP0276, accessed February 22, 2024); thus, with the exception of high-risk AI systems, for which strict liability of the user is considered the most appropriate solution, the Commission and the Parliament adhere to the fault principle, while considering it necessary to make it easier for injured parties to prove fault and causation by introducing presumptions of fault and causation, thus opting for the solution of liability for presumed fault and presumed causation. It is clear that at the level of medical liability such a solution has identical content and effects to Article 8 of the Greek Consumer Protection Law.

129 See also 73. Deutscher Juristentag. Bonn 2022, *Beschlüsse*, 6, accessed February 23, 2024, https://djt.de/wp-content/uploads/2022/09/Beschluesse.pdf, according to which the liability of the user must be formulated as liability for presumed fault corresponding to that of the provisions of §§ 831 I, 836 I BGB.

5. Conclusion

AI systems pose a significant challenge to fault-based medical liability systems. This, however, is not so much due to the substantive features of the fault principle *per se*, but rather to the general rule for allocating the burden of proof, precisely to the extent that it applies in parallel with the fault principle. According to this rule, the injured party is required to prove the facts that form the minimally required factual content of the legal rule upon which their claim is based. Namely, under a fault-based regime, they are required to prove the specific human error in the use of the system (as well as who committed it) and the causal link between the error, the output of the system, and the damage sustained.

Indeed, the fault principle in terms of substantive law seems to protect the patient to a satisfactory degree, as it imposes increased duties of care in relation to the autonomous system on the physician/hospital. However, the particular characteristics of AI (i.e. learning ability, limited predictability, complexity, opacity, and openness) create insurmountable evidentiary obstacles for the victim, who, in cases of medical liability, is at the same time confronted with difficult evidentiary problems concerning medical matters as well. These problems become even greater given the practical difficulty of accurately separating the areas of responsibility of the various subjects associated with the autonomous system in question. In the context of German law, things look very difficult for the patient, who, in order to succeed in bringing a successful liability claim, has to overcome the "black-box effect" obstacle and prove a specific fault of the physician/hospital (i.e. breach of duty of care in relation to the system), a causal link between this fault and the incorrect output of the system, and a corresponding causal link between the latter and the damage suffered. To the extent, however, that the plaintiff has an obvious knowledge deficit in relation to both medical and technical matters, it is clear that they will never be able to meet this burden of proof, with the result that they will almost always have to bear the adverse consequences of a *non-liquet* situation and, ultimately, the autonomy risk itself. On the contrary, the solution under Greek law seems to be much fairer. This is because the provisions of Article 8 of the Greek Consumer Protection Law have the effect that the physician bears the burden of proving the absence of an error and of a causal link between that (presumed) error and the damage suffered. This in turn means that the risk of any harm

resulting from the autonomous activity of the system is in case of doubt borne by the physician.

It is therefore evident that the main practical issue that one is faced with in the case of autonomous systems in medical liability is not the autonomy of the AI systems as such, but mainly the evidentiary problems arising from it. The fault principle can thus be tolerated only to the extent that the general rule on the allocation of the burden of proof is abandoned in favor of alleviations of the burden of proof in favor of the patient, since unlike the physician/hospital, the former has no control or influence whatsoever over the autonomous system, nor do they derive any financial benefits from its use. It is obvious that a purely subjective liability must give way to liability for a presumed fault (in the sense of error) and causality for it can in no way be tolerated that the patient shall bear the risk of *a non-liquet* due to the "black–box effect". Such a change seems thus imperative in pure subjective liability systems such as the German law. On the contrary, Greek law seems in this respect, even if unwittingly, innovative and certainly capable of coping with the serious evidentiary problems posed by the "black-box effect" in medicine.

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The American and Polish Legal Perspectives on Cases of Neurological Perinatal Damage – Selected Issues

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Keywords:
liability for neurological perinatal damage, no-fault system, "slice" no-fault liability models, civil compensation

Abstract: The purpose of the article is to present and analyze the method of compensation for a special type of medical damage – neurological perinatal damage – which arises in connection with childbirth and is neuropathological in nature. This damage is irreversible and the cost of medical care, which sometimes continues throughout the child's entire life, is very high. Claims involving this type of damage generate the highest compensation amounts, which means, from the liability insurance point of view, that it is a "hard-to-insure" injury. This is true for both the Polish and US liability systems, even though they are legal orders apart. What we are dealing here is, on the one hand, the need to support the family of the injured child, so that, thanks to the money obtained, they can begin their treatment and rehabilitation as soon as possible, and on the other hand, the need to take into account the interests of gynecologists and obstetricians, so that their occupations do not become deficit occupations. The idea is to increase the sense of legal security for these socially important medical professions. Given the above, attempts to seek an alternative to the judicial model of liability as a means of compensating this type of medical damage should come as no surprise. An example of an alternative liability model is the legislation enacted in two US states: Virginia and Florida (so-called "slice" no-fault liability models). These models, in effect for more than 35 years, are described in the first part of the article. In the second part, the author compares them with the main principles of the Polish judicial

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model of liability and the extrajudicial model, which, due to recent amendments to the law have undergone a major transformation. Then (due to the comprehensiveness of the subject matter), using the example of selected representative court cases, the author analyses the types of compensation claims and the amounts of benefits awarded in cases of perinatal neurological damage. The discussion ends with conclusions comparing the US and Polish models.

1. Introduction

The serious and irreversible nature of the damage to a child's health that is caused by complications and errors in perinatal care has given rise to the search for appropriate ways to compensate for this type of medical damage. Explaining the concept of neurological perinatal damage, we need to point out that, firstly, it occurs at the time of childbirth, and secondly, that it gives rise to neuropathological damage in the newborn child. The definition of this concept does not include so-called prenatal damage, i.e. damage that occurs before the child is born, during pregnancy, or even during the period before the embryo is implanted in the uterus.[1]

Perinatal neurological damage is among the most severe types of damage, and is subject to the highest amounts of compensation, especially when it comes to compensating the harm of pain and suffering of the child and immediate family members.[2] With the above in mind, and given that perinatal injury has become a "hard-to-insure" injury, so that the legal security

[1] On the broad and narrow treatment of prenatal harm, i.e., harm caused before the birth of the *nasciturus*, see: Monika Wałachowska, "Zadośćuczynienie pieniężne za krzywdę wyrządzoną w związku z leczeniem," in *System prawa medycznego*, vol. 5: *Odpowiedzialność prywatnoprawna*, ed. Ewa Bagińska (Warsaw: C.H. Beck, 2021), 841–2; Joanna Haberko, *Cywilnoprawna ochrona dziecka poczętego a stosowanie procedur medycznych* (Warsaw: Wolters Kluwer business, 2010), passim.

[2] The Polish legislator introduced by the law of 24 June 2021 on amendments to the Civil Code (Journal of Laws of 2021, item 1509) an additional compensation claim for the so-called indirectly injured persons. According to Article 446² of the Civil Code, in the event of severe and permanent bodily injury or infliction of a disorder of health, resulting in the inability to establish or continue a family relationship, the court may award the immediate family members of the injured person an appropriate sum as monetary compensation for the harm suffered. This provision can be applied to the claims of parents in the event that their child is born with a serious neurological perinatal injury, as long as the injury results in the inability

of practicing medical professions in the field of gynecology and obstetrics has been undermined, it should come as no surprise that there is a need to find an optimal model for compensating this type of injury. Classic examples of alternative models of compensation in this regard ("slice" no-fault liability models[3]) are Florida Birth-Related Neurological Injury Compensation Act (1987)[4] and Virginia Birth-Related Neurological Injury Compensation Act (1988).[5]

As indicated in the legal literature, the legal acts mentioned above were passed in response to the failure of the insurance system to cover physicians practicing obstetrics.[6] It was pointed out that the risk of perinatal neurological damage was too high and had become a so-called "uninsurable" risk for some private insurers.[7] The source of the insurance crisis was seen in the peculiarities of the insurer-insured relationship, characterized by the asymmetry of information. It was pointed out that insurers were unable to correctly estimate the risk of an insurance accident and thus inflated premiums, which led doctors to either drop insurance or switch to self-insurance.[8] It was also noted that there was a serious drop in the number of

to establish a typical family relationship with the child. The regulation came into force on 19 September 2021. More on this in sec. 3.

3 The "slice" models include, strictly speaking, specific sources of harm. These include healthcare-associated infections, vaccinations, drug-related harms, including during clinical trials and medical experiments, and perinatal neurological harms. Compare: Ewa Bagińska, "Związek przyczynowy – wielość przyczyn," in *System prawa medycznego*, vol. 5: *Odpowiedzialność prywatnoprawna*, ed. Ewa Bagińska (Warsaw: C.H. Beck, 2021), 85–91.

4 Florida Birth-Related Neurological Injury Compensation Act (1987). 766.301–316 Florida Statutes, accessed February 8, 2024, https://law.lis.virginia.gov/vacodepopularnames/virginia-birth-related-neurological-injury-compensation-act/. In short: Florida NICA.

5 Virginia Birth-Related Neurological Injury Compensation Act (1988). Virginia Statutes §§ 38.2–5000–21, accessed February 8, 2024, https://law.lis.virginia.gov/vacodepopularnames/virginia-birth-related-neurological-injury-compensation-act/. In short: Virginia NICA.

6 Jill R. Horwitz and Troyen A. Brennan, "No Fault Compensation for Medical Injury: A Case Study," *Health Affaires* 14, no. 4 (1995): 165–6; Bagińska, "Związek przyczynowy," 89–91; Kinga Bączyk-Rozwadowska, *Odpowiedzialność cywilna za szkody wyrządzone przy leczeniu* (Toruń: TNOiK, 2013), 290–8.

7 George L. Priest, "The Current Insurance Crisis and Modern Tort Law," *Yale Law Journal* 96 (1987): 1523 citing a report prepared by the US Department of Justice, Report of the Tort Policy Working Group on the Causes Extent and Policy Implications of the current Crisis in Insurance Availability and Affordability 1986, passim.

8 Priest, "The Current Insurance Crisis and Modern Tort Law," 1524.

insurers interested in selling third-party liability policies, which reduced the competition in the insurance liability market.[9]

The causes of the failure of the insurance system have particularly affected maternity hospitals and privately practicing gynecologists and obstetricians. This is because perinatal damage is linked to high compensation claims due to the fact that a child affected by neurological defects needs long-term medical care, nursing care, and rehabilitation. The huge amounts of compensation for non-material damage in the form of pain and suffering were also not without significance. This made it necessary to find an alternative way to protect members of the medical staff and medical institutions from excessive financial risks in the event of liability. It should be emphasized that, unlike other types of high-risk activity,[10] the therapeutic activity of this type, which is indispensable in society, must not lead to the phenomenon of "non-electable" of designated medical professions, possibly causing doctors to leave the profession due to excessive liability risks.[11] Therefore, in the two aforementioned states, it was concluded that the implementation of a no-fault liability system for such medical damage was the only appropriate way to respond to the crisis.[12]

To account for the motives for undertaking this study, it should be pointed out that the NICA-type program[13] has existed for more than 35 years and has been generating interest in alternative systems for the compensation of such medical damage not only in the United States, but also in European countries, including civil law countries, and therefore in

9 See more on the causes of insurance crises in the US in the area medical malpractice: Małgorzata Serwach, *Ochrona ubezpieczeniowa pacjentów przed negatywnymi skutkami leczenia* (Kraków: Medycyna Praktyczna, 2018), 41–4.

10 There are distinctions between areas of so-called dangerous medical activities, i.e. activities that generate an increased risk of harm. Areas of this type of activity include, for example, health services performed with high-tech equipment, medical experiments, or invasive clinical trials. See more: Urszula Drozdowska, *Odpowiedzialność odszkodowawcza za zakażenia związane z opieką zdrowotną* (Białystok: Temida 2, 2023), 198–205.

11 Peter C. Williams, "Abandoning Medical Malpractice," *The Journal of Legal Medicine* 4, no. 5 (1984): 581.

12 See more on *no fault* systems in a collective study, ed. Dobrochna Bach-Golecka, *Compensation Schemes for Damages Caused by Healthcare and Alternatives to Court Proceedings. Comparative Law Perspective* (Cham: Springer, 2021), passim.

13 The terms NICA program or NICA plan are commonly used in U.S. literature, because this legislation was introduced into existing state legislation in the states of Florida and Virginia.

countries with different cultures and legal traditions. In the case of NICA programs, we are dealing with legislation that has been passed in response to problems that exist in other legal orders as well. Both the need to adequately compensate victims of medical injury and the desire to avoid litigation and ensure legal security in the practice of the medical professions of gynecology and obstetrics are universal values. Therefore, the presentation of the principles of state no-fault schemes in relation to perinatal neurological damage is not only likely to arouse curiosity in the Polish reader but may also provide inspiration for the Polish legislator. In recent years in Poland, in addition to the general no-fault model, two "slice" models have emerged. The first concerns compensation for post-vaccination damages,[14] while the second concerns compensation for damages resulting from clinical trials.[15] This, in turn, means that the Polish legislator has recognized the potential of such "slice" compensation schemes. This would be a particularly interesting proposal for the professional groups most likely to be affected by it: namely, gynecologists, midwives, and their liability insurance providers.

It should be emphasized that the principles of the Polish model of liability for compensation for perinatal neurological damage, are of a general nature, as they apply to all types of medical damage. This raises the question of whether the needs to support the family of the injured child on the one hand, and to ensure the legal security of doctors and midwives on the other, are taken into account at all. In order to answer this question, the author of the article first outlines the American state legal orders, and then presents the problem of choosing between the judicial and non-judicial model in the Polish legal order. Then, based on representative court cases, she analyses the circumstances of perinatal neurological injury and the compensation benefits awarded in the judicial model. Thus, the article juxtaposes the Polish judicial model with the extrajudicial one, as well as compares it to the solutions adopted in the states of Virginia and Florida.

14 Act of 5 December 2008 on preventing and combating infections and infectious diseases in humans (Journal of Laws of 2023, item 1284, as amended), chapter 4.

15 Act of 9 March 2023 on clinical trials of medicinal products for human use (Journal of Laws of 2023, item 605, as amended), chapter 7.

2. Characteristics of Nica Programs Compared to Medical Malpractice Liability

The regulation drafted by the state of Virginia was passed after that of the state of Florida and was largely modelled on it. The two acts also have an identical axiological motivation, and can therefore be discussed together, albeit with due recognition of the differences between them.[16]

The advantage of NICA-type programs compared to the judicial route is that they do not require proving the classic prerequisites for medical malpractice liability. Tort law stipulates the need for the plaintiff to prove four main conditions of liability. Firstly, the existence of a duty of care is required; secondly, it must be demonstrated that the services of the doctor or midwife were not provided in accordance with the applicable standard of that care; thirdly, it has to be established that the relevant act or omission related to that care was the cause of the injury; and fourthly, the existence of a physically objective and ascertainable injury must be established.[17]

In the case of the NICA program, compensation cannot be claimed unless it has been established that there was a perinatal injury, i.e. an injury that occurred during childbirth or resuscitation in the immediate postpartum period. The injury should be the result of a mechanical injury (e.g., brain or spinal cord injury) or of fetal hypoxia during delivery. As a result of perinatal damage, there should be permanent physical and mental impairment. Therefore, it can be assumed that the severity of the injury is the main determinant of participation in the program. Those included in it are mostly children affected by severe cerebral palsy. Those suffering from genetic defects or congenital defects are excluded.[18] In Florida, injuries related to the birth of a live newborn weighing less than 2.500 grams (for a single pregnancy) and less than 2000 grams (for multiple pregnancies) are

16 Compare: Bączyk-Rozwadowska, *Odpowiedzialność cywilna za szkody wyrządzone przy leczeniu*, 290–1.

17 Horwitz and Brennan, "No Fault Compensation for Medical Injury," 167.

18 The origin of neurological perinatal injury is the most common cause of litigation, see, for example, the case Virginia Birth-Related Neurological Injury Compensation Programme v. Logan, Court of Appeals of Virginia, 10 June 2006, accessed February 9, 2024, https://law.justia.com/cases/virginia/court-of-appeals-unpublished/2006/1407054.html. The case concerned the etiology of childhood cerebral palsy (congenital or perinatal), which the child suffered from.

also excluded.[19] In Virginia, neurological injury at birth should also result in the child being assisted in all major life matters. Thus, we are dealing with the characteristic features of no-fault liability that distinguish it from medical malpractice liability.

The first of these features is that, compared to classic civil liability, the event to which liability is linked is defined differently. Notable is not only the fact that it is not necessary to prove fault, but also a specific construction, describing the circumstances that cause and exclude liability. Under the program, there is no need to identify the responsible doctor (possibly midwife) or their insurer since compensation is awarded from a special Fund. The parties to the proceedings are the child's representative as the applicant and the NICA Association. Secondly, the financial basis of the liability system is a special fund from which compensation is paid. This fund is financed by contributions from doctors, obstetricians, and hospitals. In addition, the funds collected are invested.[20] Participation in the programs is voluntary. However, it is worth noting that in the case of gynecologists and obstetricians, they must pay contributions (annual assessment) to be covered by the program. This is tied to obtaining a license to practice in the state.[21] The state of Virginia additionally provides for qualification procedures, evaluating the candidate in terms of his or her past professional practice and the frequency of complications associated with the practice. Namely, the Medical Commission examines past practice from the point of view of compliance with established standards of practice for a given medical specialty. It evaluates and qualifies the candidate in terms of the risks posed by his or her participation in the program. Maternity hospitals, on the other hand, are required to agree to periodic inspections by the state

19 This type of restriction is not provided for by the Virginia NICA program.

20 The problem was the classification of this fund as either private or public. Since the fund was initially endowed by state funds (in the case of Florida, to the tune of USD 20,000,000), in the litigation between NICA and MEDICAID (a public fund), NICA tried to prove that "the program is an 'arm' of the state and, as a result, is entitled to immunity." Consequently, as a "payer of last resort" NICA may not have paid for services performed by MEDICAID to program participants. This reasoning, however, has not been found adequate by the courts, including the Florida State Court of Appeals (compare: The 11th U.S. Circuit Court of Appeals ruling of 20 July 2022) More on this case further below.

21 See: information contained in NICA programs on the official websites NICA of Florida and NICA of Virginia, respectively, accessed February 9, 2024, http://www.nica.com/.

health department.[22] Thirdly, economic damage (expenses for treatment, care, transportation, rehabilitation, medical apparatus, and equipment) is primarily compensated, while non-material damage is subject to lump-sum compensation, only up to a certain amount.[23]

Since doctors covered by the NICA program will not be held civilly liable if the parents of the injured children choose the NICA system (the exclusive feature of the no-fault system[24]), both states have decided on the possibility of imposing sanctions on the doctor whose activity is linked to the compensation. A determination by the Industry Commission (in Virginia) or the Division of Administration Hearings (in Florida)[25] made under the NICA compensation procedure is forwarded to the Division of Medical Quality Assurance of the Department of Business and Professional Regulation (a division of the Department of Health). It evaluates whether standards of medical care have been violated. If violations are found, the Division can fine the doctor and even revoke his or her license to practice.[26] Despite initial objections on the grounds that this solution is too far-reaching, it was pointed out that this solution has been considered a necessary element of the program, due to the fact that doctors are not individually liable for the injury caused. Noticeable here is the attention paid to other than compensatory functions of liability for damages, it is mainly about the impact of disciplinary and preventive functions.[27] It is worth noting at this point that both authorities hearing the application rely on the opinions of experts while making their decisions. In the state of Florida, the judge uses the opinion of the Neurological Injury Compensation Programme

22 Ibid.

23 The Virginia NICA program does not provide classic compensation for non-pecuniary loss. The Florida NICA program, on the other hand, pays specified lump sums. Up to USD 250,000 is paid to directly injured persons, while up to USD 50,000 is paid to indirectly injured persons in the event of a child's death.

24 The exception is the infliction of damage through intentional fault.

25 It is noteworthy that in both states, extrajudicial bodies already in place were used, and no new bodies were created to hear the case of covering compensation for perinatal neurological injury. In Virginia, the application is handled by the commissions set up for employment injury compensation, while in Florida it is the Division of Administration Hearings, the body set up to resolve disputes over benefits, services, and actions administered by the Cabinet for Health and Family Services.

26 Horwitz and Brennan, "No Fault Compensation for Medical Injury," 169.

27 Ibid., 231.

Association, consisting of doctors and lawyers. In the state of Virginia, a three-member college of physicians appointed by the Industry Commission determines the merits of the application.

The NICA program is optional. A parent of a child born with neurological perinatal damage has the right to choose between a judicial or non-judicial route. However, if a claim is referred to NICA, the parent, as the child's legal representative, loses the opportunity to pursue a claim through the courts. At the same time, a ruling under the NICA procedure can be appealed to the District Court of Appeal for the state of Florida or Virginia, respectively, and then to the state Supreme Court (only in Virginia). This, in turn, means that there is a substantive review of the issued decision. As noted, the choice of either the NICA programme or the traditional court route is largely determined by the amount of possible compensation. If the prerequisites for medical malpractice liability are met, the choice of traditional litigation is regarded as the more favorable alternative, given the possibility of seeking redress (in the case of Virginia NICA) or obtaining a higher amount (in the case of Florida NICA). However, when the issue of medical malpractice liability is in doubt and the injury is serious, the NICA programme becomes an attractive option. The issue of providing ongoing medical care and adequate rehabilitation can thus tip the scales in the process of deciding on the choice of a claim route. However, this advantage of the program has recently been called into question following the *Cody case*.[28]

To clarify the above matter, we need to point out that, according to relevant state regulations, care for children with disabilities can be financed from various sources.[29] Thus, patients covered by NICA-type programs may simultaneously be beneficiaries of other programs, such as the MEDICAID social program.[30] As a result, the ongoing medical costs are *de facto*

[28] The case: Arven v. The Virginia Birth-Related Neurological Injury Compensation Program (1:15-cv-00870). District Court of Virginia of 26 September 2018.

[29] The US has both private and public health insurance programs, the most popular being MEDICARE, MEDICAID, or the SCHOOL CHILDREN HEALTH INSURANCE PLAN (SCHIP) program, which regulates insurance for school-aged children. It wasn't until 2010 that a federal universal health insurance plan began to be implemented, which took the name: Patient Protection and Affordable Care Act (PRACA), L. No. 11–148, 124 Stat. 119 (2010).

[30] MEDICAID is a joint federal-state healthcare program that provides coverage and benefits to low-income and disabled individuals. Under federal law, MEDICAID is generally the payer of last resort.

covered by another fund. The problem arose when the MEDICAID program questioned the financial coverage of medical procedures performed on a patient named Cody, which resulted in a dispute between the designated funds. The case ended up in federal court in the state of Virginia as a result of a lawsuit brought by Veronica and Theodore Arven; the parents of disabled Cody, acting as the so-called whistle-blowers.[31] The basic allegation was that NICA illegally passed on the cost of medical treatment for Mr. and Mrs. Arven's son to other taxpayers who were contributing to the MEDICAID social and medical assistance fund. The court, in agreeing with the parents, also considered the question of how the NICA program is supposed to secure the future care of its wards, and whether it should therefore reimburse MEDICAID for costs incurred to date. In 2018, the parties reached a settlement under which Virginia NICA paid USD 20,700,000 to MEDICAID in medical reimbursement and agreed to stop passing along such costs in the future. The plaintiffs received more than USD 4 million of the total agreed amount of USD 20,700,000 as the initiators of these proceedings.[32] On April 25,2019, Veronica Arven filed a similar claim in Florida Federal Court. As a result of the conclusion of this case (also by agreement), Veronica Arven received USD 12,750.000 as her share of the recovery of the total amount of USD 51,000,000[33] agreed upon in this case.

3. General Characteristics of the Polish System of Compensation for Medical Damage: The Problem of Choosing between the Judicial and Non-judicial Models

The basic premise for bringing a civil action or initiating proceedings under the alternative compensation[34] system is the need to verify whether the

[31] The whistle-blowers have standing to sue under the False Claims Act because of the possible depletion of federal funds for and on whose behalf they are suing. They receive a certain percentage of the winnings.

[32] Daniel Chang and Carol M. Miller, "Florida Protected OB-GYNS from Paying for Their Mistakes. The Handed Taxpayers the Tab," accessed February 1, 2024, https://www.miamiherald.com/news/politics-government/state-politics/article251785778.html.

[33] The case: United States ex rel. Arven v. The Florida Birth-Related Neurological Injury Compensation Ass'n, et al., Case No. 19-cv-61053-WPD (S.D. Fla.) District Court of Florida of 14 November 2022.

[34] In Polish law, an alternative system of compensation was established by the Act of 28 April 2011 amending the Act on Patients' Rights and Patients' Ombudsman and other acts, Journal

harm suffered by the child during childbirth was the result of conduct contrary to current medical knowledge (in the non-judicial model) or negligence on the part of the medical personnel (in the judicial model).[35] This is because the main premise of the non-judicial model is the assumption of liability for conduct contrary to current medical knowledge, whereas, in the judicial model, a gynecologist or obstetrician is liable when fault can be attributed to them (even if a medical institution is responsible[36]).

It is the sense of responsibility for the future of a person who will require long-term care, medical assistance, and rehabilitation that supports the search for causes of involuntary suffering.[37] Other reasons for medical disputes, such as higher patient awareness, high risk of harm due to inadequacies in the health care organization system, mercantilism in the practice of both the medical and legal professions, as well as the fomenting of conflicts or unreliable patient expectations by the media,[38] appear to be secondary causes in the case of this type of medical damage. Given the emergence of a serious medical injury, resulting in high costs of care with a concomitant lack of sufficient material resources for this care, it becomes quite obvious why the parents of the injured children decide to initiate proceedings.

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of Laws, No. 113, item 660. Until 30 June 2024, the proceedings were held before the Provincial Commission for Adjudication of Medical Events. Currently, the body considering the dispute regarding the occurrence of a so-called medical event is the Patients' Ombudsman.

35 As it is pointed out, the difference between these premises is not significant due to the highly objectified criteria for examining guilt in court proceedings, for more information see: Urszula Drozdowska, "Spory medyczne przed komisjami ds. zdarzeń medycznych," in *Spory medyczne*, ed. Agata Wnukiewicz-Kozłowska (Wrocław: E-publishing, Legal and Economic Digital Library, Faculty of Law, Administration and Economics, University of Wrocław, 2021), 82–90.

36 Compare Polish Civil Code, Article 430, according to which a superior is liable for a subordinate on a strict liability basis but taking into account the subordinate's fault.

37 Compare: Beata Janiszewska, "Specyfika sporów medycznych w procesie cywilnym," in *Spory medyczne*, ed. Agata Wnukiewicz-Kozłowska (Wrocław: E-publishing, Legal and Economic Digital Library, Faculty of Law, Administration and Economics, University of Wrocław, 2021), 47.

38 Agata Wnukiewicz-Kozłowska, "Wprowadzenie do problematyki sporów medycznych," in *Spory medyczne*, ed. Agata Wnukiewicz-Kozłowska (Wrocław: E-publishing, Legal and Economic Digital Library, Faculty of Law, Administration and Economics, University of Wrocław, 2021), 9–17.

In this context, therefore, it is worth noting that in the Polish judicial model, there is not only a legal assessment of the harmful event, which is binding on the parties but also, if the case is won, there is the possibility of obtaining an enforcement title authorizing effective enforcement of the awarded benefits. In the out-of-court model, in the proceedings before the Provincial Commission for Adjudication of Medical Events (hereinafter referred to as the Commission), it was determined whether a given harmful event was a medical event within the meaning of Article 67a(1) of the Act on Patients' Rights and Patients' Ombudsman.[39] Accordingly, the Commission did not award compensation benefits. Once the ruling on the determination of the existence of a medical event became final, the compensation offer was to be made by the insurer of the medical event,[40] or in the absence of insurance, by the hospital.[41]

This two-tier model of proceedings proved to be the main shortcoming of the alternative system. In practice, the offers made by hospitals tended to involve severely underestimated amounts.[42] As a result, patients reject-

[39] A medical event was the infection of a patient with a biological pathogen, bodily injury or disorder of health, or death, resulting from procedures inconsistent with current medical knowledge: in terms of diagnosis, if it caused improper treatment or delayed proper treatment, contributing to the development of the disease (1), in terms of treatment, including the performance of surgery (2), in terms of the use of a medicinal product or medical device (3). This provision, as well as the entire procedure, was repealed by the Law of 16 June 2023, Journal of Laws, item 1675. For more information see: Leszek Bosek, "Commentary to Articles 67a et seq. Law on Patients' Rights and Patients' Ombudsman," in *Ustawa o prawach pacjenta i Rzeczniku Praw Pacjenta. Komentarz* [*Act on Patient's Rights and Patient's Rights Ombudsman. Commentary*], ed. Leszek Bosek (Warsaw: C.H. Beck 2020), 725–38.

[40] The insurance was conceived as first-party insurance. Because insurers significantly inflated premiums, hospitals found it difficult to purchase insurance policies. As a result of pressure from hospitals, compulsory insurance became optional insurance. See more: Serwach, *Ochrona ubezpieczeniowa pacjentów przed negatywnymi skutkami leczenia*, 304–5.

[41] This model applied only to medical events that took place in the hospital. Recently, there has been a further narrowing of the subject matter of the proceedings. Proceedings before the Patients' Ombudsman apply to hospitals that provide so-called guaranteed health services, i.e., services under contract with the National Health Fund (NHF), the public body established to organize and finance health services under the universal health insurance system. Hospitals that provide services commercially have therefore been excluded from the out-of-court system.

[42] There have been absurd situations, such as offers in the amount of one zloty. This occurred when the treatment entity did not agree with the committee's ruling at all.

ed these offers,[43] and took their claims to courts. The Commission model began to be regarded as a kind of "pre-judgement" or "evidence hunting"[44] because the proceedings before the Commission enabled patients to prepare for a confrontation in court at a relatively low cost.[45] Admittedly, the court was not bound by the findings of the Commission, however, thanks to the proceedings before the Commission, the party initiating the litigation had at its disposal, the opinions of experts, the testimony of witnesses, and the reasoning behind why the Commission accepted the incompatibility of a given procedure with current medical knowledge. Thus, the assumed rule that the model would not apply to cases of serious medical damage (including cases of serious perinatal neurological damage) proved true only in part. Cases of serious medical damage have also been the subject of Commission proceedings due to the uncertainty regarding the outcome of litigation inherent in medical cases.

Following the creation of a public compensation fund for victims of medical events, the Polish out-of-court model has been transformed. First, the definition of a medical event has been amended, indicating that it can be any event (in the form of infection, bodily injury, disorder of health, or death) as long as it could have been avoided with a high probability if the health service had been provided in accordance with current medical knowledge or if another available diagnostic or treatment method had been used, unless there were foreseeable normal consequences of the method to which the patient gave informed consent. Second, proceedings before the Patients' Ombudsman end with an administrative decision establishing the existence of a medical event and either awarding a certain lump sum

43 Serwach, *Ochrona ubezpieczeniowa pacjentów, przed negatywnymi skutkami leczenia*, 340.

44 Kinga Bączyk-Rozwadowska, "Koncepcja *no fault compensation* a polski system kompensacji szkód, doznanych w następstwie zdarzeń medycznych," in *Współczesne problemy prawa zobowiązań*, ed. Adam Olejniczak et al. (Warsaw: Wolters Kluwer, 2015), 91.

45 The application fee was fixed and amounted to only PLN 200. The cost of expert opinions was also low. The Decree of the Minister of Health of 23 December 2011 on the lump sum of costs in the proceedings before the Provincial Commission for the Adjudication of Medical Events (Journal of Laws No. 294, item 1740) set the rate for the issue of an opinion at PLN 300. It was subject to an increase of PLN 150 if the opinion was prepared by a person with the academic title of professor, PLN 100 – with the title of associate professor, PLN 60 – with the degree of doctor. These amounts made it impossible to find an expert willing to write an opinion.

as compensation or denying compensation.[46] Thus, the idea of alternative proceedings has changed diametrically.[47] Proceedings before the Patients' Ombudsman take on an administrative-legal character. At the same time, compensation is paid by a public fund, which is financed primarily with deductions from universal health insurance premiums.[48] As a result, neither hospitals (which are primarily public hospitals) nor their insurers bear any financial burden, both before the medical event (e.g., in the form of a premium) and after it has occurred.[49]

As with a civil court judgment, the decision is enforceable. However, the difference between proceedings ending in a civil court judgment and proceedings before the Ombudsman ending in an administrative decision is that, as in Commission proceedings, the patient may not accept the proposal contained in the decision of the Patients' Ombudsman,[50] considering it unsatisfactory.[51] The danger of treating the proceedings before the Patients' Ombudsman as a kind of "pre-judgment" arises here as well, especially in the case of serious medical damage, such as perinatal neurological damage. As it seems, pre-determining whether a case can end in a win is still a tempting prospect for medical lawyers and their clients. Hence the need for a brief overview of the new course of proceedings.

The proceedings are initiated by an application to the Ombudsman (subject to a fixed fee of PLN 300). The first requirement of alternative proceedings regarding low cost and thus accessibility has been met. In the case of perinatal neurological damage, the application may be filed by one of the

46 Cf. Article 67za of the Act on Patients' Rights and Patients' Ombudsman.

47 This issue clearly demonstrates the interpenetration of private law and public law norms in medical law. For the definition of medical law see: Zbigniew Banaszczyk, "Properties and Elements of a Private Medical Law Relation – General and Methodological Premises," in *Medical Law*, ed. Leszek Bosek (Warsaw: C.H. Beck, 2019), Legalis.

48 Cf. Article 67zi (3) of the Act on Patients' Rights and Patients' Ombudsman.

49 As it seems, this circulation of "public money" explains why only hospitals with contracts with the National Health Service (NHS) are beneficiaries of this arrangement.

50 With the acceptance of the offer, the applicant (the patient, the legal representative of a minor patient, or a close relative, in the event of death) waives legal redress. Cf. Article 67zc of the Act on Patients' Rights and Patients' Ombudsman.

51 The amounts are as follows: for infection with a biological pathogenic agent or bodily injury or health disorder from PLN 2,000 to PLN 200,000. In the event of a patient's death, compensation to relatives ranges from PLN 20,000 to PLN 100,000.

parents acting as the child's legal representative.[52] The application shall be accompanied by a copy of the medical records in the applicant's possession and other documents confirming the described facts, or detailed information if such documents are not available.[53]

The child's legal representative makes three statements. The first is a declaration that no civil proceedings for compensation, pension or damages are pending or have not been finally concluded in the case covered by the application. The second is a declaration that the criminal court has not ordered reparation for the harm caused by the crime or for the harm suffered, or for restitution to be made to the child. The third is that the child has not obtained compensation, pension, or reparation from the person responsible for the damage, including the liability insurance provider. The latter statement prevents obtaining compensation benefits from the responsible party and from the public compensation fund at the same time. The first and second statements preclude simultaneous conducting of judicial and extrajudicial proceedings. In addition, for the duration of the proceedings before the Ombudsman, the course of the statute of limitations for claims for compensation for damage resulting from the medical event to which the application relates does not begin, and the one that has begun is suspended.[54] This provision suggests that there is no obstacle to initiating civil proceedings after proceedings before the Ombudsman, especially if the Ombudsman issues a decision proclaiming the absence of a medical event. In turn, in the event of a decision favorable for the applicant, another important issue arises; namely, the possibility for a civil court to use the expert opinion that formed the basis of the Ombudsman's decision. Of course, this possibility will arise only if the legal representative, in response to the decision awarding the benefit, does not accept the proposed benefit

52 Cf. Article 67t (2) in conjunction with Article 67u of the Act on Patients' Rights and Patients' Ombudsman.

53 According to Article 67y of the Act on Patients' Rights and Patients' Ombudsman, the Ombudsman is the controller of the data contained in the documentation in connection with the proceedings. The Medical Incident Compensation Fund Benefits Team, established at the Ombudsman, is authorized to process the records (including electronic records) to the extent necessary for the preparation of an opinion.

54 Cf. Article 67w (2) of the Act on Patients' Rights and Patients' Ombudsman.

on behalf of the minor patient.[55] In that case, he does not have to make a statement waiving all claims for compensation, pensions, and damages that may arise from the medical event (Article 67zc of the Act on Patients' Rights and Patients' Ombudsman).[56]

At this point, it should be noted that under Article 278[1] of the Polish Code of Civil Procedure,[57] a civil court may admit evidence of an opinion prepared at the request of a public authority in other proceedings provided for by the law. The main purpose of such a solution is to reduce the likelihood of duplication of activities of experts, who often prepare several opinions on the same case. In this context, it is worth highlighting the following points.

Firstly, the Patients' Ombudsman, according to Polish law, is an organ of central government administration (Article 42 (1) of the Act on Patients' Rights and Patients' Ombudsman), which means that it meets the requirement of being a public authority. As has been pointed out, the Ombudsman does not conform to the classic model of an ombudsman independent of the executive branch.[58] The powers conferred on him by the legislature

55 Pursuant to Article 67 zc (1) of the Act on Patients' Rights and Patients' Ombudsman, the applicant shall submit to the Ombudsman a statement of acceptance of the compensation benefit or renunciation of the compensation benefit within 30 days from the date the decision becomes final.

56 This raises issues that cannot be elaborated on within the scope of a short article. First, whether the parents' statement of abandonment of the claim (without the consent of the guardianship court) is legally effective, and second, whether, given the developmental nature of perinatal neurological damage, the statement is affected by the lack of awareness on the part of the parents. It should also be emphasized that the declaration of waiver of claims can only apply to damage disclosed up to the date of the application. Therefore, the amount awarded could be considered to compensate for damage only to the basic needs of the child. This type of interpretation is supported by the very short deadlines for filing a claim (1 year counted from the date of the damage becoming apparent, 3 years counted from the date of the event). Taking into account the fact that parents find out about their child's serious neurological defects quite quickly (usually within a few days after childbirth), the dates of the two deadlines coincide (cf. Article 67t (3) of the Act on Patients' Rights and Patients' Ombudsman). This, in turn, means that the court route would be permissible to the extent of damages that became apparent after the date of filing the application.

57 Act of 17 November 1964 – Polish Code of Civil Procedure, Journal of Laws of 2023, item 1550, as amended. In short: Pol. Civ. Proc. Code.

58 For more information on the legal status of the Patients' Ombudsman, see: Leszek Bosek, "Opinia o projekcie ustawy o ochronie indywidualnych i zbiorowych praw pacjenta oraz o Rzeczniku Praw Pacjenta," in *Zmiany w systemie ochrony zdrowia w procesie*

are of a mixed nature, i.e. they are characteristic of ombudsman's powers, as well as those of the executive branch (e.g., in terms of imposing fines on medical institutions in the event of violations of the collective rights of patients[59]). Secondly, the Ombudsman conducts proceedings to determine a medical event under the law. Thirdly, the provision of Article 278[1] of the Polish Code of Civil Procedure does not use, with reference to a document prepared in other proceedings, the concept of an "expert opinion," but speaks only of an "opinion." Therefore, it can be assumed that the opinion of the Medical Event Compensation Fund Benefits Team,[60] composed of specialists in medical science on the occurrence of a medical event and its consequences, meets the requirements of the provision under review.[61]

It should be noted that the application of Article 278[1] of the Polish Code of Civil Procedure would lead to a significant shortening of civil proceedings. The positive impact of this provision has another dimension too. It undoubtedly provides an additional incentive to initiate proceedings before the Ombudsman for the sole purpose of "probing" whether an action before the court is likely to succeed.

Proceedings before the Ombudsman are proceedings that are expected to be completed within a relatively short time. According to Article 67za (3) of the Act on Patients' Rights and Patients' Ombudsman, a decision is issued within 3 months of receiving a complete and properly paid application. In doing so, the Ombudsman relies on the opinion of the Team, which in turn has 2 months to prepare it. Thus, the requirement for speed of alternative proceedings is fulfilled. The procedure before the Ombudsman does not provide for hearings involving parties or witnesses. The provision of Article 67z of the Act on Patients' Rights and Patients' Ombudsman only allows the applicant to be summoned to provide information, explanations, and documents necessary for the consideration of the case. Similarly, the

legislacyjnym (283), Przed pierszym czytaniem, no. 4 (2008): 21; Urszula Drozdowska and Marcin Śliwka, "Analiza statusu prawnego Rzecznika Praw Pacjenta – zagadnienia wybrane," *Zeszyty Prawnicze Biura Analiz Sejmowych Kancelarii Sejmu* 47, no. 3 (2015): 9–34.

59 Article 68 et seq. of the Act on Patients' Rights and Patients' Ombudsman.

60 The Team consists of at least 20 members practicing in the medical profession, including at least 15 members practicing in the medical profession. The opinion is given in the composition, not more than 3 members.

61 Cf. Article 67x of the Act on Patients' Rights and Patients' Ombudsman.

Ombudsman may request information, explanations, and documents from the health care provider that are in the applicant's possession. The proceedings are therefore conducted in writing and do not confront the patient and the health care provider with each other, which is currently considered debatable in the context of alternative proceedings.[62]

The compensation benefit is paid within 14 days from the date of submission of the statement of acceptance of the compensation benefit. The healthcare provider to whose activities the application is related is informed of the Ombudsman's positive decision (on the determination of the medical event and payment of the compensation benefit). As a result, it is obliged to analyze the root causes of the medical event and formulate and implement recommendations to take measures to improve the quality and safety of the health care services provided in order to prevent a recurrence of the medical event, unless an analysis has already been carried out in this regard (Article 67zd of the Act on Patients' Rights and Patients' Ombudsman).

Only the applicant is entitled to file an appeal.[63] Since the payment is awarded from the compensation fund, it was considered that the hospital is not a party to the proceedings and has no right to appeal the decision on the occurrence of a medical event. This approach may be questionable, if only because the procedure can be treated by the claimant as a kind of "pre-judgment" and used in a later claim.

4. Analysis of Litigation for Compensation for Neurological Perinatal Injury

Given the severity of the neurological perinatal injury, the petitioner's choice of the judicial model seems to have been a foregone conclusion anyway. Even if the proceedings before the Ombudsman end with a positive decision on the occurrence of the medical event and the compensation offer is made, the highest possible amount of compensation of PLN 200,000 cannot meet the needs of the child affected by neurological perinatal injury. As a result,

62 Drozdowska, *Odpowiedzialność odszkodowawcza za zakażenia związane z opieką zdrowotną*, 501–2.

63 The appeal is filed with the Appeals Board for Medical Event Compensation Fund Benefits. Cf. Article 67ze et seq. of the Act on Patients' Rights and Patients' Ombudsman.

the parents are unlikely to accept the offer and will likely take the case to a court of law.

Two distinctive court of appeal rulings, made relatively recently (in 2021 and 2022), will be presented below. These cases illustrate the range of compensation claims and give us an idea of the benefits being awarded. They also indicate the prerequisites for liability for damages, which are the building blocks of liability.

The tort victim who is in a state of harm due to severe perinatal neurological injury is entitled, as any person suffering an injury in the form of bodily injury and disorder of health, to monetary compensation under Article 445 of the Polish Civil Code.[64] However, such persons are not able to use the compensation received. The compensation awarded to an impaired person under Article 445 of the Polish Civil Code, therefore, in essence, benefits those who provide care to that person. Perhaps this circumstance meant that for a long time, in Poland, there was no basis for awarding compensation to anyone other than the injured person.

The system of compensation for medical damage currently in force in Poland[65] includes, in addition to the above-mentioned compensation for the impairment of health and injury to the body of the directly injured person (Article 445 §1 of the Polish Civil Code), compensation to relatives for the death of the injured person (Article 446 §4 of the Polish Civil Code) and the above-mentioned compensation to the immediate family member of a person with whom a family relationship cannot be established

64 Act of 23 April 1964 (Journal of Laws of 1964, No. 210, item 2135, as amended). In short: Pol. Civ. Code.

65 Despite the absence of a statutory basis, some common courts and even the Supreme Court (compare: judgment of the Supreme Court of 27 March 2018 (ref. III CZP 60/17)) have awarded compensation to immediate family members for the loss of family ties. This was made possible by the approach recognizing the family bond as a personal good, subject to protection under Article 448 of the Pol. Civ. Code. However, this concept was challenged in the Supreme Court's judgment of 22 October 2019 (ref. I NSNZP 2/19), which gave rise to Article 446^2 of the Pol. Civ. Code. Similarly, a violation of a patient's rights gives rise to the possibility of awarding damages under Article 448 of the Pol. Civ. Code (compare: Article 4(1) of the Act of 6 November 2008 on Patients' Rights and Patients' Ombudsman, Journal of Laws of 2009, No. 52, item 217, as amended). The issue of violation of the patient's right to health services corresponding to the requirements of medical knowledge (in the case of errors in the conduct of childbirth) remains, due to its extensiveness, beyond the scope of consideration.

or continued as a result of the tort (Article 446^2 of the Polish Civil Code). The latter regulation entered into force on 19 September 2021.[66]

As a result, in cases involving compensation for severe perinatal neurological damage, we have to deal with the so-called "multiplicity", i.e. multiple claims raised by the plaintiff.[67] In addition to claims for compensation for the harm, property claims are made for medical, care, and rehabilitation expenses incurred (Article 444 §1 of the Polish Civil Code),[68] as well as a claim for payment of compensatory pension (Article 444 §2 of the Polish Civil Code).[69]

Another characteristic feature of the medical lawsuits in question is the high value of the claims that are raised and subsequently awarded.[70] The claim for compensation in favor of the directly injured person is usually the highest.[71] In comparison, the claim for compensation in favor of the child's parents or siblings as indirectly injured persons is significantly lower. By way of example, in the justification of the judgment of Courts of Appeal in

66 Based on Article 2 of the Law of 24 June 2021 on amendments to the Civil Code, the new provision applies to torts that occurred also before 19 September 2021 (retroactive nature of the provision).

67 The plaintiffs will be, in addition to the minor child (represented by the parents), the parents, and even siblings as the closest relatives of the injured party. Both the feature of "multi-claims" mentioned in the main text and the multi-subjectivity are characteristic of medical trials; Janiszewska, "Specyfika sporów medycznych w procesie cywilnym," 47–54.

68 According to Article 444 §1 of the Pol. Civ. Code, in the event of physical injury or impairment of health, compensation for damage shall cover all resulting costs. At the request of the victim, the indemnitor should pay in advance the sum needed for the cost of medical treatment, and if the victim has become an invalid, also the sum needed for the costs of training for another profession.

69 According to Article 444 §2 of the Pol. Civ. Code, if the injured party has completely or partially lost his or her earning capacity, or if his or her needs have increased or his or her future prospects have diminished, he or she may demand an appropriate pension from the indemnitor.

70 The plaintiffs demanded PLN 1,000,000 in compensation for the directly injured party, and PLN 200,000 for each of the parents and brother of the directly injured party (a total of PLN 600,000). In addition, they claimed damages in the amount of PLN 7,591.99 and annuities in various amounts for the periods prior to the lawsuit, including for the future. Separately, claims for interest on account of delay were raised, and a request was made to establish liability for the future.

71 With the proviso that, at the request of the injured party, a lump sum of one-time compensation may be paid in advance as an annuity. In such a case, this amount may exceed the amount of the compensation. Cf. Article 444 § 3 of the Pol. Civ. Code.

Warsaw of 19 May 2022,[72] we read that the compensation for the directly injured plaintiff amounted to PLN 1,000,000, while the compensation for his next of kin (parents) amounted to PLN 200,000 for each of them.[73]

The facts of the case show that the plaintiff was born with severe cerebral palsy as a result of an acute central nervous system hypoxia occurring during delivery as a result of the umbilical cord being wrapped around the baby's neck. The medical institution responsible for the treatment was accused of a significant delay in restoring the baby's circulation and gas exchange, as well as of stopping replacement ventilation and extubating too early, without ascertaining the state of circulation and the quality of gas exchange. The experts pointed out unequivocally that the CTG records dictated that a cesarean section be performed quickly, which was not done. In doing so, they ruled out the possibility of harm from intrauterine septic shock. As a result of the negligence described above, the child suffers from quadriparesis, symptomatic epilepsy, lower limb seizures, myoclonic seizures, and balance and motor coordination disorders. The child is also incapable of verbal communication, lacks manual dexterity, and is in severe pain. The child also experiences so-called muscle tearing while falling asleep and during sleep, which means that, when asleep, the child has to be accompanied by the mother, who cannot sleep through the night for this reason.

Since the Court of Appeal in Warsaw was ruling after the entry into force of Article 446^2 of the Polish Civil Code, this Court took up the key considerations for the interpretation of this provision regarding the necessity of determining whether the state of the child's health allows for establishing typical family ties with those closest to him or her, or for the continuation of such ties. In the court's view, this requires the examination of the child's state of consciousness, in accordance with the rules of evidence, to

72 Ref: V ACa 34/21, Legalis.

73 These are the amounts resulting from the judgment of the Warsaw District Court (ref. II C 277/13). The first instance judgment was made before the amended provision of Article 446^2 of the Pol. Civ. Code came into effect. Accordingly, PLN 200,000 was awarded to each of the parents for the violation of family ties based on the content of Article 448 of the Pol. Civ. Code. The brother of the directly injured party received PLN 180,000. The Court of Appeal in Warsaw, as a court of second instance, referred the case for reconsideration in this regard, indicating that the court of first instance was to reconsider the prerequisites for compensation set forth in Article 446^2 of Pol. Civ. Code. This was possible due to the retroactive nature of this provision, since the injurious event (childbirth) took place on 22 August 2010.

determine whether consciousness can arise in the injured person allowing the person to establish such bonds with relatives. Therefore, in this regard, the Court of Appeal in Warsaw referred the case back to the lower court as a court *meriti*.[74]

Although in the Polish legal system, the system of universal health insurance finances ongoing health care for children up to the age of 18,[75] as is clear from the wording of the justification of the Court of Appeal in Warsaw, the incurred, as well as future costs of care and rehabilitation of the minor turned out to be only partially covered by the National Health Fund and other charitable organizations, which are not legally obliged to cover them. The amount of the pension, therefore, covered the costs associated with the use of appropriate medical equipment (in the injured person's home) and professional assistance using a variety of methods of neurological rehabilitation. In particular, the cost of dolphin therapy was considered reasonable. As a result, the District Court in Warsaw[76] awarded a pension in the amount of PLN 6,343.00 per month for the period from April to November 2013, then the amount of PLN 9,115.50 per month for the period from December 2013 to February 2020, and the amount of PLN 12,513.78 per month for the period from March 2020 and for the future.

It is worth noting that the periods mentioned of the pension above are indicative of the protracted nature of the proceedings. The lawsuit was

74 As it seems, the accumulated evidence made it possible to recognize the claims of indirectly injured parties in this regard. Although the judgment of the District Court was based on the wrong legal basis (Article 448 of the Pol. Civ. Code), it was compliant with the law. The premise of the inability to establish or continue family ties contained in Article 446^2 of the Pol. Civ. Code does not apply to those seeking compensation, i.e. the parents (because they undoubtedly loved their disabled child), but to the directly injured person. On the other hand, from the wording of the justification it appears that: "Sometimes J. just smiles. He doesn't point fingers at anything. He doesn't talk. He does not communicate his needs and does not walk at all. Brother J. makes attempts to establish any contact with him. However, the effects are limited, as the District Court found, to eye contact and infrequent smiles in J.'s facial expressions."

75 Under the Act of 27 August 2004 on health care services financed from public funds (Journal of Laws, No. 210, item 2135, as amended) children are treated as family members of the insured, which refers to any person with citizenship of an EU or EFTA member state, or the United Kingdom, residing in these countries.

76 Ref: II C 277/13. The amount of the pension was upheld by a judgment of the Court of Appeal in Warsaw.

filed on 3 April 2013,[77] the judgment of the District Court was rendered on 20 October 2020, and the judgment of Appellate Courts in Warsaw was issued on 19 May 2022. In total, the case took nine years, including one year and six months in the second instance.[78]

Similarly, in the second case presented, which was resolved by the judgment of the Court of Appeal in Gdańsk on 21 April 2021,[79] the proceedings lasted eight years.[80] The amount of compensation demanded for a child born with asphyxia as a result of a delayed cesarean section was significantly higher than in the case heard by the Court of Appeal in Warsaw. It amounted to PLN 2,500,000. In this case, however, the damage was even more severe. The child had been diagnosed with encephalopathy, involving global psychomotor retardation, internal four-chamber hydrocephalus, bilateral optic nerve atrophy, microcephaly, quadriparesis with decreased muscle tone and bilateral pyramidal signs, thermoregulatory disorders, and chronic respiratory failure (the child was permanently attached to a ventilator).

As for the claim for compensation for the indirectly injured, it concerned the parents and two siblings. Since the Court of Appeal in Gdańsk ruled before the provisions of Article 446^2 of the Polish Civil Code came into effect, the benefits were based on the content of Article 448 of the Polish Civil Code. They amounted to PLN 50,000 (for each person). Due

77 Pursuant to Article 442^1 §1 of the Pol. Civ. Code, a claim for compensation for damage caused by a tort is time-barred at the expiration of three years from the date on which the injured party learned, or by exercising due diligence could have learned, of the damage and the person obligated to repair it. However, this period may not be longer than ten years from the date on which the event causing the damage occurred. The limitation contained in the last sentence, however, does not apply to personal injury, the limitation period for which, according to Article 442^1 §3 of the Pol. Civ. Code, cannot end earlier than the expiration of three years from the date on which the injured party learned of the damage and the person obligated to repair it.

78 In the Polish civil process, it is possible to request security for a claim for an annuity by obliging the defendant to pay periodically specified sums already in the course of the proceedings. Such a possibility was applied in the case at hand. In this connection, the civil liability insurer demanded a limitation of its liability.

79 Ref. I ACa 867/20, Legalis.

80 The process was filed on 12 February 2013, the Court of Appeal in Gdańsk, as the court of first instance, issued judgments on 20 October 2020 (XVC 1912/12). The case was considered by the Court of Appeal in Gdańsk for 6 months.

to the degree of influence of other factors (not attributable to the entity responsible for the treatment, as determined by the courts, there was a percentage reduction in the sums awarded in respect of all compensation claims (both property and non-property, in favor of directly and indirectly injured persons). Thus, the case is all the more interesting from the point of view of the analysis of perinatal neurological damage, because, as it turns out, the American concept of proportional liability is put into practice in Polish jurisprudence.

This concept is founded on the idea of proportional distribution of the burden of damage between the defendant and the plaintiff, which makes it possible to allocate responsibility for the damage, according to the degree of probability of the influence of certain factors on its occurrence.[81]

In the case under review, the Regional Court in Gdańsk found, relying on expert opinions, that the very poor condition of the child after delivery was the result of not only obvious negligence in the form of failure to perform a cesarean section in time, but also a probable intrauterine infection. Accordingly, it accepted a "contribution" (for factors other than negligence) at the level of 40% and drastically reduced the sums of the claims awarded to the directly and indirectly injured parties.

The Court of Appeal in Gdańsk, on the other hand, found that the percentage contribution of causes other than the defendant's negligence in childbirth adopted by the District Court was too high and revised it to 20%. Unfortunately, it is not clear from the reasoning of the Court of Appeal in Gdańsk how the courts determined these mathematical proportions[82]. It is therefore difficult not to criticize this reasoning, especially since the experts who gave opinions in the case pointed to other causes that could have affected the final extent of the damage, without operating with numbers. In light of the above, the following criticisms arise.

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[81] Ewa Bagińska, "Teoria odpowiedzialności częściowej (proportional liability jako koncepcja sprawiedliwego rozłożenia ciężaru odpowiedzialności deliktowej – wprowadzenie do problematyki," *Gdańskie Studia Prawnicze* 35 (2016): 51; Bagińska, "Związek przyczynowy," 665–6.

[82] Within the framework of cumulative causation, the District Court assumed that cause 1 (poorly conducted delivery) contributed to the occurrence of the effect with a 60% probability and cause 2 (intrauterine infection) contributed to the occurrence of the same effect with a 40% probability. In turn, according to the Court of Appeal, cause 1 constituted 80%, and cause 2 – 20% of the total damage.

Firstly, in light of the possibility that the cause of the injury was different from that alleged, the adequacy (normality) of the causal relationship between the cause of the injury alleged in the lawsuit and its effect should be questioned.[83] Note that based on the District Court's calculations, in light of the accepted theory of adequate causation,[84] one may wonder whether the first cause (misconduct at childbirth) contributing to the effect with a probability of no more than 60% should be considered legally relevant at all and result in the award of any claims for damages.[85]

Secondly, the issue of cumulative or alternative causation is typical of the so-called medical cases. In cases of this type, one often encounters a possible alternative series of causes that could also have led to the damage.[86] There are basically two situations. Alternative causation means that the damage results from many causes, and one of the causes may be attributed to the medical institution, while others are included in the so-called natural or injured sphere. In the case of alternative causation, each of the causes, due to its real impact, is capable of causing a violation of the injured party's legal rights. Therefore, the court should determine whether the cause indicated by the plaintiff is capable of causing damage.

Cumulative causation is characterized similarly in the sense that it is a type of competition of causes[87] and covers a situation in which the damage resulting from an event results from the joint action of two or more causes, but it is not possible to determine with certainty to what extent the damage

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83 Drozdowska, *Odpowiedzialność odszkodowawcza za zakażenia związane z opieką zdrowotną*, 431–7.

84 On the theory of adequate causation, see: Andrzej Koch, *Związek przyczynowy jako podstawa odpowiedzialności odszkodowawczej w prawie cywilnym* (Warsaw: PWN, 1975), passim.

85 The Polish law does not apply the percentage-based method of examining natural causation, typical of common law systems. The occurrence of an effect with only 51% probability does not allow for the assumption of a causal relationship, as is the case in common law systems. Compare: Ewa Bagińska, *Odpowiedzialność odszkodowawcza w razie niepewności związku przyczynowego* (Torun: TNOiK, 2013), 53–4.

86 See also considerations by Agata Wnukiewicz-Kozłowska and Urszula Drozdowska, "Causal Effect Relationship in Medical Cases. An Old Problem in a New Scenario. Commentary to CJEU Judgment (Second Chamber) of 21 June 2017, N.W. & Others v. Sanofi Pasteur MSD & Others, Case C-621/15, EU:C:2017:484. Approbative Gloss," *Review of European and Comparative Law* 46, no. 3 (2021): 263–90.

87 Koch, *Związek przyczynowy*, 202–7.

resulted from a specific cause.[88] Therefore, unlike alternative causation, a single cause would not have caused the harm in its entire scope, or would not have caused a harmful effect at all.[89] A typical example of this type of situation is a factual situation in which the causes of an event cannot be separated. At the same time, one of them remains, for example, in the zone controlled by the medical institution (e.g. surgery or another medical institution), while the second one remains in the natural sphere (e.g. the condition of the injured person due to which the person was hospitalized), and the third one, e.g. in the injured sphere (susceptibility to a given disease).

The position of the Polish law on this type of coincidence of causes is based on the assumption that the probability of establishing an effect should be considered only in relation to the cause of a given type (raised by the plaintiff), regardless of the fact that this effect resulted from other events at the same time.[90] The starting point is an appropriate reconstruction of the facts, which may result in the assumption of liability or the dismissal of the claim (in line with the all-or-nothing rule) due to objective uncertainty regarding the examination of the causal relationships in medicine.[91]

Thirdly, in the light of the civil law doctrine, neither a health predisposition nor injured party's initial health condition are treated as co-causes of the damage, much less as factors enabling the patient to have contributed to causing the damage (see Article 362 of the Polish Civil Code).[92] The causes included in the so-called natural sphere for which no one is responsible should therefore not result in a reduction of the due compensation if it is

88 Ewa Bagińska, "Odpowiedzialność cywilna w sytuacji tzw. przyczynowości kumulatywnej w świetle nowych kierunków rozwoju orzecznictwa," in *Z badań nad prawem prywatnym. Księga Pamiątkowa dedykowana Profesorowi Andrzejowi Kochowi*, eds. Adam Olejniczak, Marcin Orlicki, and Jakub Pokrzywniak (Poznań: Wydawnictwo Naukowe UAM, 2017), 28.

89 Maciej Kaliński, *Szkoda na mieniu i jej naprawienie* (Warsaw: C.H. Beck, 2008), 36–9.

90 Koch, *Związek przyczynowy*, 137.

91 Thus, *de lege ferenda*, one can consider adopting the concept of partial responsibility as corresponding to the sense of justice. However, it should be borne in mind that the concept of a high degree of probability that a given cause is causally related to the damage, used so far in Polish medical cases, usually results in the awarding of full compensation. On the other hand, thanks to the adoption of the concept of proportional liability in a situation where the injured party had little chance of receiving compensation (in accordance with the all or nothing rule), this proposal would give the person a chance of obtaining some compensation.

92 Drozdowska, *Odpowiedzialność odszkodowawcza za zakażenia związane z opieką zdrowotną*, 460–70.

established with a high degree of probability that the cause in question for which the medical entity is responsible could have caused the damage.

To sum up, the judgment of the Court of Appeal in Gdańsk is in contradiction of the views presented so far in the legal doctrine as well as of the previous jurisprudence of civil courts.[93]

Meanwhile, the approach to compensation for neurological perinatal injuries under no-fault systems, which do not provide for partial liability, is different. The event of a child being born with perinatal asphyxia is considered in the context of possible perinatal events involving mechanical trauma, i.e. damage to the brain or spinal cord, or fetal hypoxia during delivery. Since hypoxia undoubtedly occurred during delivery in the case under review, NICA programmes would most likely accept responsibility for compensating for the damage. Similarly, the described event would meet the conditions for a medical event within the meaning of Article 3 section 1 point 11 of the Law on Patients' Rights and the Patients' Ombudsman. According to this provision, a medical event is a bodily injury or health disorder[94] that could have been avoided with a high probability if health services were provided in accordance with current medical knowledge or if another available diagnostic or treatment method was used.

5. Conclusions

Although it exists in a very different context, the Polish judicial model has similar drawbacks as the American one, which include the lengthiness of the proceedings (as demonstrated by the two cases presented), the great uncertainty in establishing liability in terms of proving both fault and causation. As a result, similar objections to the judicial model and arguments in favor of no-fault liability as those outlined in the American literature can be formulated.

However, the shortcomings of the Polish judicial model, in the case of the occurrence of serious medical damage (and perinatal neurological damage is one of these), do not invalidate its importance. As the considerations

93 Ibid.

94 The legislator also mentions death and infection with a biological pathogen. These consequences are out of the question if a child is born with deficits caused by perinatal neurological damage.

outlined above have demonstrated, this model, due to the significant amounts awarded directly and indirectly to the victims, still represents the best response to the occurrence of serious perinatal neurological damage. The advantages of the Polish alternative procedure, such as its low cost, accessibility, and speed, cannot hide its basic disadvantage which is the fact that the upper limit on benefits awarded to the injured parties is too low.

Comparing sums awarded in the cases we have discussed with the amounts provided for in the Polish out-of-court model, it should be made clear that the PLN 200,000, which was the highest sum offered here, cannot even compensate for the property damage resulting from a serious perinatal neurological injury. This compensation scheme can only be used if applicants need to "probe" the possibility of winning in traditional civil proceedings. Note that, unlike the no-fault models of the states of Virginia and Florida, the applicant decides to reject the compensation offer only following the Ombudsman's decision. Thus, the choice to proceed before the Ombudsman does not lead to the abandonment of the judicial path at the outset, as happens when the case is accepted for hearing by the Industry Commission (in Virginia) or the Division of Administration Hearings (in Florida), respectively. What also draws attention when we compare it to the US model is the lack of mandatory participation in the fund by entities that have a vested interest in taking the burden of liability off their shoulders; namely, hospitals that have contracts with the NHF and their liability insurers. This is the case, even though these entities are the main beneficiaries of the solution.

In conclusion, the considerations outlined above have demonstrated that the main problem of the Polish no-fault model will continue to be the question of the amount of compensation awarded. Therefore, in the case of a serious perinatal neurological injury, the Polish no-fault model will not provide a satisfactory alternative to the judicial model for the injured patients and their families. The solutions it provides are general and, as such, do not reflect the specifics of neurological perinatal injury. Thus, the juxtaposition of the Polish and American perspectives clearly indicates the superiority of "sectional" no-fault models such as those dedicated to particular types of medical damage over general models, at least in cases of specific damage of major severity. This is unfortunate, because 35 years of experience in running NICA-type programs have shown that such programs,

above all, enable safe medical practice. The lengthy proceedings and high costs associated with litigation (especially when the outcome is uncertain) have made the NICA program an interesting alternative for parents of children with serious neurological defects resulting from childbirth, including compensation for serious property damage. The revealed "abuses" related to NICA MEDICAID's failure to pay for medical care provided to the program's clients (which involved a *de facto* deterioration in the quality of that care) had the effect of undermining parents' confidence in the program. To prevent this, in 2021, Florida raised the limits on one-time compensation from USD 100,000 to USD 250,000. In the event of a child's death, the one-time compensation of USD 10,000 was raised to USD 50,000. Subsequently, the number of directors (NICA board members) was increased from five to seven to include a parent (possibly a legal guardian) of a NICA participant and a representative of an organization that supports people with disabilities to ensure the proper operation of the program. This means that the programs are learning from their mistakes.

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Portuguese Health System – Challenges in Times of Genomics

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Abstract: This article presents the Portuguese health care system that combines the National Health Service, health subsystems and private health insurance. Genomic medicine is expanding the scope of its activity, and its main challenges in pre-natal medicine and post-natal healthcare will be presented here and it will be discussed whether a private health insurance system can provide genomic medicine. As the Four "Ps" concept of Medicine is increasingly relevant, it is important to check if the private system can accommodate this evolution.

1. The Right to Health Care in Portugal

The social right to health protection shall be guaranteed by the National Health Service (*Serviço Nacional de Saúde*, SNS), according to the original version of the Constitution of the Portuguese Republic of 1976 (*Constituição da República Portuguesa*, CRP). The Minister of Social Affairs, Dr António Arnaut, created the SNS through Law No. 56/79 of 15 September 1979.[1]

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[1] Unlike Article 35 of the Charter on Fundamental Rights of the European Union (Health care) and Article 3 of the Convention on Human Rights and Biomedicine, which mentions "Equitable access to health care", the Portuguese Constitution requires that access to health

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The first Basic Health Law dates to 1990[2] and, recently, Law No. 95/2019 of 4 September 2019 has taken its place.[3] The 2019 Basic Health Law aims to reinforce the central and crucial role of the patient, reinforcing patient's rights and centrality, recognizing the importance of patient associations and their representation, as well as their importance in achieving health and recognising the importance of genomic medicine.

2. Health Insurance in Portugal

In Portugal, three different systems coexist: (1) the National Health Service (known as the SNS), (2) health subsystems (social health insurance systems for certain professional groups such as security forces, health workers, and state [ADSE] and banking [SAMS] sectors[4]) and (3) voluntary health insurance, between private parties and insurers.

There are three types of insurance contract:[5] (1) reimbursement (expenses are borne by the insured person, who can request full or partial reimbursement from the insurer), (2) assistance (managed care, where there is a network of services that the insurers themselves provide and recommend to the insured) and (3) a combination of the previous two. In the market, Low-cost Health Insurance is also available – despite being commonly referred to as a "health plan", it is a health card that offers *discounts* on certain health services, such as dental care.[6]

be effective, following the Beveridge model, with financing based on taxes and providers being predominantly public (Article 64 of the CRP).

2 Law No. 48/90 of 24 August 1990, amended by Decree-law No. 185/2002 of 20 August 2002.

3 Jorge Simões, Inês Fronteira, and Gonçalo Figueiredo Augusto, "The 2019 Health Basic Law in Portugal: Political Arguments from the Left and Right," *Health Policy* 125, no. 1 (January 2021): 1–6.

4 This is a figure originating from the Bismark Model. These are funds fed by contributions paid by their potential beneficiaries or by those who are their relatives. The contributions they make to a given fund give them and their family members access to health care from selected providers.

5 *Regime Jurídico do Contrato de Seguro* (RJCS) – Decree-law No. 72/2008 of 16 April 2008, most recently amended by Law No. 82/2023 of 29 December 2023.

6 According to the *Autoridade de Supervisão de Seguros e Fundos de Pensões* (supervisory authority of insurance services), these are products that work within a network of providers and allow the customer to access a set of health services at a lower price, without the assumption of risk by the platform managing the health plan (or health card).

The number of people holding private health insurance reached almost 3.6 million in 2023,[7] which equates to over a third of the Portuguese population. The number of those insured under health policies rose by 3.3% in the first 6 months of the COVID pandemic. In 2023, the rise in inflation meant that private health care insurance prices rose by 6.7%,[8] and are expected to continue to increase throughout 2024.[9]

Thus, access to health services varies. Around 40% of Portuguese people are covered under a public or private health subsystem or private health insurance.[10] However, this service is *additional* (complementary) to the one provided by the SNS, especially regarding the type of care provided: private hospitals and clinics are mainly sought to provide consultations with specialist doctors. This means that, in 2020, despite the increasing representation of private health care in Portugal, the bulk of health care services were provided by public hospitals. For example, 65% of all surgical interventions, 84.2% of all auxiliary diagnostic and therapeutic tests, 67% of radiological exams and 75.1% of births were all conducted in public hospitals.[11] In fact, preventive care, public health policies and major health interventions are, above all, a field of action of the National Health Service.

A closer look at the economic-financial level will provide a clearer idea of the real magnitude of the difference between the two sectors. Regarding the sale of insurance, the market increased by 8.3% in 2020, to almost 950 million euros. By comparison, the Budget (consolidated revenue) of the Ministry of Health was 12,565.4 million euros in 2021 and has reached a record budget of 15.000 million euros in 2024.

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7 "Há quase 3,6 milhões de pessoas com seguro de saúde em Portugal," *Observador*, 10 December 2023, accessed May 17, 2024, https://observador.pt/2023/12/10/ha-quase-36-milhoes-de-pessoas-com-seguro-de-saude-em-portugal/.

8 Data retrieved from EcoSeguros, "INE calcula que prémios dos seguros de saúde aumentaram 6,7% este ano," 18 December 2023, accessed May 17, 2024, https://eco.sapo.pt/2023/12/18/ine-calcula-que-premios-dos-seguros-de-saude-aumentaram-67-este-ano/.

9 Carolina Ribeiro, "Seguradoras vão aumentar os preços dos seguros de saúde," *CNNPortugal*, 10 January 2024, https://cnnportugal.iol.pt/videos/seguradoras-vao-aumentar-os-precos-dos-seguros-de-saude/659ea2210cf25f99539372f2.

10 A. Mateus et al., *Sector Privado da Saúde em Portugal, Millenium BCP e Augusto Mateus & Associados* (2017), 9.

11 *Instituto Nacional de Estatística - Estatísticas da Saúde: 2020*, INE, 2022, 25.

Nevertheless, the role of private health financing is still very relevant in Portugal, mainly due to direct payments, particularly to cover medication costs. Voluntary health insurance and other out-of-pocket costs borne by families account for 36.6% of the total health expenditure in Portugal. Compared to other OECD countries, this is a very high value[12] and has a regressive impact on society, as poor individuals spend relatively more on medication and healthcare than well-off members of society.

3. Limitations of Health Insurance Contracts

The National Health Service (SNS) is responsible for providing access to health care. Health insurance is an *additional* resource and not an *alternative*. Therefore, the principle of private autonomy and contractual freedom is firmly maintained, which has its reverse in the *pacta sunt servanda* rule (Article 406 of the Civil Code). Therefore, health insurance contracts have serious limitations in their scope of protecting the right to health.

3.1. Expenses over Insurance Ceilings

Private customers can choose between three plans with different coverages and prices, which vary depending on the options selected and the insured person's age.[13] For hospital health care, the operator offers coverage between €15,000 and €500,000. In other words, if treatments exceed these values, the insurance company is no longer responsible for paying for the services.[14] For this reason, it is common, particularly in oncology, for patients to leave hospitalization (of their own free will or compelled by the private provider) or to abandon the therapeutic plan they were carrying out relying on health insurance, and then having to be placed a possible waiting list for treatments offered universally and free of charge by the SNS.[15]

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12 OECD, "Health Spending (Indicator)," 2024, accessed May 17, 2024, https://doi.org/10.1787/8643de7e-en.

13 This information was obtained from one of the key players in the insurance market.

14 According to a Lisbon Court of Appeal decision of 7 June 2018, within the scope of a health insurance contract, the Insurer may only be responsible for covering expenses up to the maximum amount of coverage stated in the policy in question. Also, the Insurer shall not be held liable for damages to the Insured that result from non-compliance with the insurance contract. (Proc. 7983/15.4T8LSB.L1–6.).

15 André Dias Pereira et al., "White Book On Cancer Patients´ Rights: Portugal," in *White Book on Cancer Patients' Rights*, eds. Anne-Marie Duguet and André Dias Pereira

3.2. Non-renewal of the Insurance Contract

Regarding the renewal of the contract, if not stipulated otherwise, the contract is valid for one year and automatically renewed if neither party declares their desire to terminate it, through a written statement sent to the other party at least 30 days before the date on which the contract would be renewed (in accordance with Article 115, No. 1, of the RJCS). Therefore, if the insurer realizes that the risks to the insured's health have worsened – for example, because a request has been made for the reimbursement of treatment expenses for a serious illness, which could involve relevant costs – the insurance company will inform the insured that it does not intend to renew the contract. In such cases, Article 217 applies. Its protection is very weak. It only states that in the event of the non-renewal of the contract or coverage, if the risk is not proportionally covered by a subsequent insurance contract, the insurer shall not, for two subsequent years (after the event of non-renewal), refuse to cover expenses resulting from the manifested illness (or any other health care expense *related* to it) as well as expenses related to any other event that occurred throughout the term of the contract. Therefore, the insurer must cover these expenses if they were initially covered by the insurance policy and up to the maximum amount of coverage provided for in the contract and still left over on the last period of contract validity (Article 217/1). Moreover, the insurer must be informed of the illness within 30 days following the end of the contract, unless there is a reasonable impediment that justifies a delay (Article 217/2).[16]

Consequently, the insurer will only provide services until the insured capital from the last period of validity of the contract is exhausted. It is understood that, if it were not for Article 217/1, the insurer would never bear these risks. This is a specific rule for health insurance contracts. If there is no subsequent contract (or if there is, it does not have identical protection to cover that disease), the insurer is by law obliged to cover the expenses

(ONCONET SUDOE Project WP 3–3, June 2019), 2–34, https://www.onconet-sudoe.eu/media/attachments/2020/08/18/whitebook_patients-rights.pdf; and André Dias Pereira et al., eds. *Cadernos da Lex Medicinae - n.º 2 | Cancro e Direito* (Coimbra: Instituto Jurídico – Faculdade de Direito da Universidade de Coimbra, 2018). Available at: https://www.centrodedireitobiomedico.org/publica%C3%A7%C3%B5es/publica%C3%A7%C3%B5es-online/cadernos-da-lex-medicinae-n%C2%BA-2-cancro-e-direito.

16 Maria Inês Oliveira Martins, "Seguros e Doença Oncológica," in *Cadernos da Lex Medicinae*, 24.

resulting from illnesses manifested during the validity period of that insurance contract.

3.3. Limits to the Duty of Providing Information

The policyholder and the insured are obliged to declare all circumstances that may be relevant to risk assessment by the insurer before the contract is concluded. The insurance provider usually prepares a questionnaire for the prospective client, which might not mention all health issues relevant to the insured. If other circumstances relevant to the assessment of the applicant's risk exist that were not included in the questionnaire, the applicant must provide such information to the insurance provider. The insurer has the obligation (or risks incurring civil liability) to clarify to the interested party this duty of providing information and the consequences of non-compliance (Article 24 of the Law on Insurance Contracts).

Article 25 stipulates that intentional omissions or inaccuracies from the policyholder may lead to the contract being declared void by the insurance company. As clarified by Portuguese jurisprudence, "It is legitimate for the insurance company to cancel the insurance contract in cases where the insured person knowingly omitted relevant data about their health."[17]

Selling insurance is not even conceivable without standardizing the terms and conditions.[18] Article 3 of the Law on Insurance Contracts stipulates that legislation on unfair contractual terms,[19] consumer protection and distance contracts also applies to insurance contracts. The unfair contract terms regime can be invoked, to both control what is included in the contract (whether the insured understood its terms and conditions) and to assess the content of the terms (for example, a clause that stipulates a period of eight days to submit a reimbursement request). On the other

17 Évora Court of Appeal Decision of 13 July 2017, Proc. 1846/13.5TBSTR.E1; Already in 2007, the same Court stated that diabetes is likely to influence the terms of a life insurance contract, thus if when answering the questionnaire about their health, which was part of the life insurance proposal they subscribed, the insured omitted the fact they had diabetes, the contract is void according to Article 429 of the Commercial Code – Tribunal da Relação de Évora, Judgement of 25 January 2007, Proc. 10091/2006–2.

18 Maria Inês Viana de Oliveira Martins, "O controlo do conteúdo das cláusulas contratuais gerais no contrato de seguro," *Revista Thesis Juris–RTJ* 9, no. 2 (2020): 416.

19 Law on General Contractual Terms (Decree-law No. 446/85 of 25 October 1985, last updated by Decree-law No. 123/2023 of 26 December 2023).

hand, the Law on Insurance Contracts itself is cautious in relation to health insurance, considering its special risk, and imposing some requirements.

In health insurance, the insurer covers the policyholder's risks related to health care that do not correspond to the agreed benefits or the expenses incurred in each year of contract validity if a random event provided for in the same contract occurs, obliging the same policyholder to pay the corresponding price.

Pursuant to article 216 of Decree-Law No. 72/2008, pre-existing illnesses, unknown to the insured person at the date of the contract, are covered by the coverage agreed by the insurer, and may be restored by agreement to the contrary; however, the contract may provide a grace period not exceeding one year to cover these diseases.

If the contract ceases to be valid as a result of non-renewal and if the risk is not covered under the subsequent insurance contract, the insurer shall not, in the two years following the termination and until the insured capital has been exhausted in the last period of contractual validity, refuse to provide benefits resulting from illness or other health care benefits related to the term of the contract, as long as they are covered by insurance (Article 217(1)).

3.4. Health Insurance in the Basic Health Law – Reinforcement of the Duty of Information

Bearing in mind the low protection provided by health insurance, the 2019 Basic Health Law (Article 27) reinforced the duty of information setting some basic requirements:

1) subscribing to an insurance or health plan must be preceded by the insurer providing clear and intelligible information regarding the conditions of the contract, i.e. the scope, exclusions and coverage limits, including information on possible interruption or discontinuation of health care provision if the contractual insured coverage limits are reached;
2) health establishments are required to inform users about the costs of health care services when patients have subscribed to insurance and health plans. This includes informing about the costs of the entire proposed medical intervention (except when the institutions justifiably do not have the necessary elements to provide this information). The contract must therefore be *clear* about what is covered by the insurance

and what is excluded, how the contribution is made (total or partial), coverage caps, deductible values, the deadlines to submit the reimbursement request and what that process entails;

3) requirement to provide clarifications regarding the age limit criterion. Lifetime health insurance is currently excluded in Portugal, individuals must be warned that, after a certain point in their lives, they will not be able to enter a health insurance contract and, if one is in force, it will terminate without the possibility of renewal. Most insurance contracts do not allow people over 60, 65 or – in exceptional cases – over 70 years old;[20]
4) the insured must be informed that there will be an interruption or discontinuation of health care provision if the contractually established maximum limits are reached. Health establishments are also required to provide information to avoid financial "surprises" at the end of treatment or hospitalization.

3.5. The Right to Insurance after the Treatment of a Serious Illness – The "Right to Be Forgotten" – An Incomplete Legal Reform

In an effort to improve the legal level of protection of those citizens who wish to be *additionally* protected through a health insurance contract, the Parliament enacted an important Law, which unfortunately is not yet applicable due to lack of regulation.[21]

Law No. 75/2021 of 18 November 2021 introduced several changes to Law No. 72/2008.[22] It reinforces the right of people who have overcome or mitigated situations that posed an increased risk to their health or have had a disability, to access credit and insurance contracts, thus prohibiting discriminatory practices and establishing the "right to be forgotten."[23]

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20 Cf. Sofia N. Silva, *Os Seguros de Saúde Privados no contexto do Sistema de Saúde Português* (Associação Portuguesa de Seguradoras, 2009), 42.

21 Luís Poças, "A Lei 75/2021, o direito ao esquecimento e os seguros," *Revista de Direito Comercial* (2022); on this issue, see also an article: "Lei do Direito ao Esquecimento aguarda há dois anos por ser regulamentada e cumprida," Portal de Informação Português de Oncologia Pediátrica, December 13, 2023, accessed May 17, 2024, https://www.pipop.info/lei-do-direito-ao-esquecimento-aguarda-ha-dois-anos-por-ser-regulamentada-e-cumprida/.

22 Law No. 72/2008 (the Law on Insurance Contracts or RJCS) was amended in 2015, 2021 (by Law No. 75/2021) and, most recently, in 2023 (through Law No. 82/2023).

23 The previous law which prohibited discrimination based on disability or increased health risk (Law No. 46/2006 of 18 November 2006) did not include anti-discrimination rules

This right has long been claimed by survivors of pediatric cancer and other patients who have mitigated situations of increased health risk and those who overcame a disability and allows them access to various financial products, such as life insurance or bank credit, without being compelled to declare that they had an illness posing a substantial risk to their health.[24]

Discriminatory practices that violate the principle of equality are forbidden (Article 15 of the Law on Insurance Contracts). This follows the general rule *prohibiting discriminatory practices* and enforcing the principle of equality laid down in Article 13 of the Constitution. Discriminatory practices, such as charging different premiums to those with a disability or increased health risk are not allowed. Yet, as the Law is not yet regulated, health insurance is not yet adequate for the health protection of those citizens.[25]

designed to protect those who *overcame* an increased health risk or a disability. Therefore, the 2021 Law – influenced by French law – increases its scope of application by widening the concept of "increased health risk." Francisco Rodrigues Rocha, "O 'direito ao esquecimento' na lei n.º 75/2021, de 18 de Novembro: breves notas," *Revista da Faculdade de Direito da Universidade de Lisboa* 63, no. 1–2 (2022): 341–64.

24 Law No. 75/2021 prohibits discriminatory practices, enshrines the "right to be forgotten" and allows cancer patients who have overcome or mitigated situations of aggravated health risk or a disability to have, as consumers, the "right to be forgotten" when taking out loans to acquire housing or consumer credit, as well as in the contracting of mandatory or optional insurance associated with said credits. The law also ensures that they shall not be subject to an increase in the insurance premium or exclusion of guarantees from insurance contracts, and no health information relating to the medical situation that gave rise to the increased health risk or disability may be collected or processed by credit institutions or insurers in a pre-contractual context. The law imposes some requirements, namely relating to the time frame in which the treatment ended: 10 years must have passed since the end of the therapeutic protocol in the case of an increased health risk or disability that has been *overcome*; 5 years – since the end of the therapeutic protocol, if the medical condition occurred before the age of 21; or 2 years of continued and effective therapeutic protocol are required in the case of increased health risk or disability that is being *mitigated*. The Law does not aim to impose the principle of equality (where all situations are treated equally) but rather ensure that similar situations are treated similarly, and a different procedure is adopted for different situations, ensuring the observance of the principle of equity.

25 Despite having come into force on 1 January 2022 (Article 8), Law No. 75/2021 still has certain aspects relating to insurance activity that require regulation by the Government. According to Article 7 of the Law, this regulation should have been completed before 1 January 2023. This delay has motivated the Assembly of the Republic to issue a Resolution recommending that the Government should regulate to make Law No. 75/2021 operative. But, as yet (April 2024), no Regulation or Ordinance has been published.

3.6. Health Insurance Is Not an Instrument for Universal Coverage

In conclusion, Portuguese law continues to entrust the National Health System (SNS) with an increasing responsibility for health care provision. Health insurance, increasingly common in Portuguese society, still has many usage limits and is freely revocable – by the insurance company after one year. It is not, therefore, seen as a life-long "health plan" or long-term solution that protects citizens who suffer from serious and/or chronic illnesses, especially as their health concerns increase with age.

With this legal and societal framework, resulting from a certain level of legal traditionalism, no clear lines of consumer protection for people who acquire health insurance have been developed. The general principles of private law still govern many aspects of health insurance, with the additional regulation of the law on general contractual terms and conditions and sector regulation.

4. Genomic Medicine

4.1. From the Human Genome Project to the Three Ps (Predictive, Preventive and Personalised) Medicine

In the 1990s, the study[26] of topics related to genetic engineering in the field of law began, along with the establishment of ethical and legal rules.[27] Launched in October 1990 and completed in April 2003, the Human Genome Project accelerated scientific research in clinical genetics.

Nowadays, genomics is thriving, thanks to gene editing technologies such as CRISPR/Cas9 that allow the genome of any organism, including humans, to be modified in a controlled manner.[28] Moreover, in the field of human genome analysis, there have been advances in genetic tests, performed at a very reasonable cost and with a very significant level of reliability and precision. In the context of healthcare provision, genetics, combined with artificial intelligence, is opening doors, with "personalised" and

[26] Guilherme de Oliveira, "Implicações jurídicas do conhecimento do genoma," *Revista de Legislação e Jurisprudência* 129 (1996): 325–32.

[27] At the level of the Council of Europe (Convention on Human Rights and Biomedicine), and UNESCO (Universal Declaration on the Human Genome and Human Rights of 1997 and the International Declaration on Human Genetic Data of 2004).

[28] André Dias Pereira, "Gene Editing: A Challenge for Homo Sapiens," *Medicine and Law* 36, no. 4 (December 2017): 5–28.

"precision" models with clear gains in terms of effectiveness and safety of treatments opening the door to the predictive preventive and personalized medicine – 3PM.[29]

In human health,[30] the applications of genomic medicine are essentially divided into two areas: reproductive medicine and post-natal preventive and therapeutic interventions.[31] Its cost and its implications represent an ethical, legal, and economic challenge to publicly funded health care and are probably out of reach for the private insurance legal scheme in force in Portugal.

4.2. Genomics and Reproductive Medicine: Prenatal Diagnosis and Preimplantation Genetic Diagnosis

Advances in biotechnology and early diagnosis have been posing tremendous ethical challenges to the legal good of intrauterine life and are contributing to an expansion of the so-called *individual or liberal eugenics*, centered on individual choices, resulting in the transfer of the "decision-making axis from politicians to parents."[32] In this context, the legal norms should safeguard human dignity, the physical and psychological integrity of women and the protection of the embryo.

In Portugal, pre-natal tests are allowed[33] and abortion is legal up to 24 weeks of pregnancy, in case of serious fetal malformation (Article 142 Penal Code).[34]

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29 Fernando J. Regateiro et al., "Promoting Advanced Medical Services in the Framework of 3PM—a Proof-of-Concept by the 'Centro' Region of Portugal," *EPMA Journal* 15 (2024): 135–48, https://doi.org/10.1007/s13167-024-00353-9.

30 The CRISPR/Cas technique is also used in animals, plants, and environmental changes in agriculture, biofuel production, modification of endangered animal species, food characteristics, etc. – Bill Gates, "Gene Editing for Good: How CRISPR Could Transform Global Development," *Foreign Affairs* 97, no. 3 (May/June 2018): 166–70. Cf. Thaís Cesa e Silva, *A Edição Genética como elemento das responsabilidades parentais: Uma antecipação do cenário juscivilístico familiar face aos avanços da Engenharia Genética* (Coimbra: Instituto Jurídico, 2021).

31 André Dias Pereira, ed., *Medicina Personalizada de Base Genómica, Boas Práticas, Ética e Direito* (Coimbra: Coimbra University Press, 2023).

32 Jürgen Habermas, *The Future of Human Nature* (Cambridge: Polity, 2003).

33 Ordinance No. 5411/97 of the Ministry of Health.

34 Article 142 permits abortion if it is performed by a doctor and in the following scenarios: (1) abortion is the only method to avoid the risk of death or grave physical or mental harm

Concerning Preimplantation genetic diagnosis (PGD), Law 12/2006 accepts it in Article 29: for people from families with mutations that cause early death or serious illness, when there is a high risk of transmission to their offspring.[35] The National Council of Ethics – 51/CNECV/07 – stated in 2007 that:

> The use of the DGPI puts into conflict ethical values that may come into conflict in certain circumstances. When it is possible to avoid the development of a human being who has a high probability of being born with or developing a serious illness, which leads to premature death and prolonged suffering and is irreversible, the use of DGPI can be positively valued from the point of ethical view.

These ethically problematic technologies are provided both in the public and the private sectors. In the public sector, there are some difficulties in accessing PGD, since there is a long waiting list.[36] In the private sector, this very expensive procedure is paid out of pocket, as insurance companies (normally) do not offer this service.

4.3. Post-natal Genomic Medicine

This sphere of medical activity is very large and growing, and poses serious challenges for a health system. The Medicine of the Three Ps (1. Prevention 2. Prediction 3. Personalization [to which one shall add a fourth P – 4. Participation]) is one of the outcomes of Genomic Medicine. This evolution implies

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to the mother; (2) abortion is recommended in order to avoid the risk of death or permanent grave physical damage to the mother – up to the 12th week of pregnancy (3) the foetus is at risk of grave illness or malformation – up to the 24th week of pregnancy; (4) the pregnancy was caused by rape or sexual assault – up to the 16th week of pregnancy; (5) at the mother's choice – up to the 10th week of pregnancy. In cases where the foetus is not viable, abortion can be performed at any time during pregnancy. Any of the conditions mentioned above must be certified by a doctor, except item 5, in which case the mother has to submit an affidavit to a doctor or clinic stating that her decision was "mindful and responsible". If the mother is under 16 years old or mentally incapacitated, the consent to perform an abortion has to be provided by the woman's legal representative (usually parents).

35 The National Council for Assisted Reproductive Technology decides *case by case* and the medical indications for possible PGD are determined by current good practices and are included in the recommendations of national and international professional organisations in the area and are reviewed periodically.

36 See opinion 98/CNECV/2017 – Opinion on Waiting Lists When Carrying Out Pre-Implantation Genetic Diagnosis (Pgd).

the proper management of individual genomic data, a practice guided by the demands of legal and ethical principles, particularly data protection.

The advantages often attributed to personalized medicine are: (1) identifying diseases earlier (accurate diagnosis), (2) reducing treatment burdens, and (3) tailoring treatment to the patient (pharmacogenomics).

However, personalized medicine is not without its problems. The widespread sharing of personal databases and biobanks created for biomedical research, as well as the scientific results obtained, raises questions about the right to confidentiality of this information and the privacy of participants. Thus, confidentiality and privacy in the clinical context may be affected, and there may be a violation of the right not to know one's own genetic information. Moreover, it requires expensive resources and qualified personnel.

Predictive and presymptomatic genetic tests must have strong legal protection, as they contain familial information, (potentially) definitive/permanent information, and information with potential discriminatory effects. Therefore, predictive genetic information that is particularly sensitive includes: (1) Potentially *permanent* genetic information because it is (potentially) unchangeable throughout life; (2) *Familial* genetic information, as it provides a lot of information about ancestors, descendants, and about close relatives, which raises social, psychological, ethical, and legal issues; and (3) *Predictive* genetic information, as it can provide information that a certain healthy person will suffer (in the case of monogenic diseases) or with some probability will suffer (multifactorial diseases) from a certain serious disease, which can be a source of disturbance in personal, family and professional life, and in relationships with institutions, such as insurers. Since 2005, Law 12/2005 has protected people against discrimination based on genetic grounds, specifically in the context of (life and health) insurance, labor and adoption. However, in their actual practice insurance companies normally exclude patients with genetic diseases, either through the investigation of family history or after the onset of the symptoms by not renewing the insurance contract.

Insurance companies continue to violate an old law, Law 12/2005, which in Article 12 (4) states that "Insurance companies cannot demand or use genetic information obtained through the collection and registration of the client's family history as a reason to refuse the subscription of

an insurance, to charge a higher premium or for any other purposes." This is a daily practice and the competent Authorities do not intervene in a clear violation of the Law and the duty not to discriminate based on an individual's genetic profile, also established in the Constitution and the Convention on Human Rights and Biomedicine.[37]

4.4. Gene Therapy

Furthermore, genomic medicine may offer somatic gene therapies and germline gene therapies.

4.4.1. Somatic Gene Therapies

Regarding *somatic line therapies*, good news continues to emerge, offering hope for many people and families affected by severely disabling genetic diseases, causing immense physical, psychological, and social suffering. In this context, one should highlight phase 1 or 2 clinical trials that, in the last 10 years, have included the use of genomic editing (targeting in vivo or ex vivo somatic cells) for treating diseases such as sickle cell anemia, β-thalassemia, genetic blindness, some forms of cancer, diabetes, urinary tract infections, familial amyloid polyneuropathy, hereditary angioedema and HIV/AIDS.

Somatic gene therapy has been ethically and socially accepted, only requiring strict adherence to the classic rules of biomedical research, with a strong emphasis on risk-benefit decision-making. In Public Law, but also Insurance Law, it mainly raises issues related to the principles of equity and (bioethical) justice, due to the high cost of drugs produced based on it. In fact, one may wonder if such medications are affordable for private insurance companies in a market as small and unregulated as the Portuguese one.[38] On the other hand, how far can the SNS afford such high costs? So far, the Portuguese National Health System has been able to accommodate innovative therapies. In the last 5 years, over 260 innovative medicines were

[37] Article 11 – "Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited."

[38] Recently, the FDA approved a drug based on gene editing that costs 3.5 million dollars – Michael Cook, "The World's Most Expensive Drug Is a Cure for Haemophilia," *BioEdge*, November 29, 2022, accessed May 17, 2024, https://bioedge.org/public_health/the-worlds-most-expensive-drug-is-a-cure-for-haemophilia/.

incorporated into clinical practice with co-participation or full payment of costs by the State.[39]

4.4.2. Germline Gene Therapy

As for germline gene therapy, its use is very controversial. It should be noted, however, that, despite the prohibitionist basis set out in Article 13 of the Convention on Human Rights and Biomedicine, drawn up in 1997, over the last few years there has been a progressive acceptance[40] of the use of germinal genetics, i.e. if the intervention is carried out with therapeutic purposes for the subject (embryo) of the therapy and their descendants (avoiding diseases such as Huntington's disease, Portuguese Familial Paramyloidosis and – in the future – even diabetes, hypertension etc.), this may prove to be acceptable, as long as the technique is safe, which is not yet the case.[41]

Concerning somatic or germline genetic editing for *enhancement* purposes, it is prohibited by international documents and international organizations.[42]

The UNESCO International Bioethics Committee, in October 2015, called on member states to accept a moratorium on modifications to the germline through genetic editing.[43]

In 2017, the National Academy of Sciences and the National Academy of Medicine of the USA stated: "Germline interventions, within strictly

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39 See: Agência Lusa, "Mais de 260 medicamentos inovadores entraram no arsenal terapêutico nacional em 5 anos," *Observador*, July 23, 2023, accessed May 17, 2024, https://observador.pt/2023/07/23/mais-de-260-medicamentos-inovadores-entraram-no-arsenal-terapeutico-nacional-em-5-anos/.

40 Portuguese Basic Health Law (Basis 11) is open to future progress, stating: "The State recognises the importance of genomics in the context of public health, and the law must regulate genomics for therapeutic purposes, carrying out tests and knowledge base of data for the provision of healthcare and research, in compliance with the following principles: (…) e) Freedom of scientific research in genomics, taking into account its importance for the improving the health of individuals and humanity."

41 See: André Dias Pereira, "Gene Editing: Portuguese Constitutional, Legal and Bioethical Framework," in *Rechtliche Aspekte der Genom-Editierung an der menschlichen Keimbahn. Veröffentlichungen des Instituts für Deutsches, Europäisches und Internationales Medizinrecht, Gesundheitsrecht und Bioethik der Universitäten Heidelberg und Mannheim*, eds. Peter Axer et al. (Berlin: Heidelberg, 2019), https://doi.org/10.1007/978-3-662-59028-7_14.

42 Eduardo António da Silva Figueiredo, *Desagrilhoar Prometeu? Direito(s), Genes e Doença(s) – Desafios Constitucionais na Era da Engenharia Genética* (Lisboa: Petrony, 2020).

43 The Council of Europe's Bioethics Committee Declaration on Genome Editing Technologies of 2 December, 2015.

regulated risk limits and when coupled with accompanying research on the risk, were ethically defensible if the intervention constituted 'really the last reasonable option' for a couple of having their own healthy, biological child." In other words, the official position on such interventions shifted from "not allowed as long as the risks have not been clarified" to "allowed if the risks can be assessed more reliably." This represents rather an extraordinary methodological and hermeneutic inversion. From prohibition, it moved to a moratorium and then to conditionality.

In September 2017, international concerns, notably expressed by the German Bioethics Committee were that "speculations now concentrate less on whether but rather only on when the first human genetically modified by genome editing will be born."[44]

In November 2018, it was announced in China that twin girls with genome modifications in the germline had been born. On 29 November 2018, the CNECV took a public stance, condemning this event.[45] In recent years, there have been no reports of other human rights violations through genetic editing of embryos.

In December 2018, the World Health Organization (WHO) established an advisory committee of global and multidisciplinary experts (the Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing) to examine the scientific, ethical, social and legal challenges associated with (somatic, germline, and hereditary) human genome editing.[46]

Also, the UNESCO panel of experts calls for the prohibition of "editing" human DNA to avoid unethical manipulation of hereditary traits,

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44 Deutscher Ethikrat Berlin, 29 September 2017.

45 "Manipulação Genética em Embriões humanos através do uso de técnicas de edição de genoma," Conselho Nacional de Ética para as Ciências da Vida, November 29, 2018, accessed May 17, 2024, https://www.cnecv.pt/pt/comunicacoes/manipulaco-genetica-em-embries.

46 Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing; As a result of this committee's work, in 2021, WHO issued new recommendations. It emphasises the need to avoid the premature use of genetic editing in humans. See: World Health Organization, *WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing. Human Genome Editing: Position Paper*, 2021; World Health Organization, *WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing. Human Genome Editing: A Framework for Governance*, 2021.

stating: "Gene therapy can be a watershed in the history of medicine, and genome editing is undoubtedly one of the most promising endeavors of science for the benefit of all humanity."[47]

Will the prohibition continue to be imposed on couples who increasingly invoke procreative freedom, the "right" to have healthy offspring provided with "well-being" – arguments that can mobilize the very Declaration of the World Health Organization (WHO) from 1946, which states: "Health is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity." Others go further and even foresee the legal duty of a family to seek healthy offspring, using technological means available in a particular society. Thus, it is also necessary to revisit Savulescu's thesis on the moral obligation of parents to choose the best possible genetic constitution for their children, which leads some authors to foresee the future fit of a parental legal obligation to resort to genetic interventions for preventive-therapeutic purposes.[48] Regarding the challenges that genetic editing poses to society and law, it is important to recall Jonas's words: "Act in such a way that the effects of your action are not destructive of the future possibility of such life."[49]

5. Conclusion

Genomic medicine brings new hopes and fantastic advancements in the struggle for a healthier life. It allows couples to embrace a reproductive project with the hope of having a healthy child, it cures severe diseases, and it makes it possible for individuals to prevent illnesses or to adopt an adequate medication and lifestyle. However, this predictive preventive personalised (and participatory) medicine requires strong and stable financing and the democratic engagement of all stakeholders, and also respect for

47 "Universal Declaration on the Human Genome and Human Rights," UNESCO, accessed May 17, 2024, https://en.unesco.org/themes/ethics-science-and-technology/human-genome-and-human-rights.

48 Julian Savulescu, "Procreative Beneficence: Why We Should Select the Best Children," *Bioethics* 15, no. 5/6 (2001): 414–26; Julian Savulescu and Guy Kahane, "The Moral Obligation to Create Children with the Best Chance of the Best Life," *Bioethics* 23, no. 5 (2009): 274–90. Silva, *A Edição Genética*.

49 Hans Jonas, *Technology, Medicine and Ethic, On the Practice of the Principle of Responsibility* (Frankfurt, 1990).

the human rights of all citizens, irrespective of age, health condition, health risks, and genetic heritage.

The National Health Service is struggling to respond to these complex challenges. On the other hand, the private insurance sector – as it is nowadays organized in Portugal – does not seem to be prepared to face these challenges with some compassion.

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Legal Regulation of Surrogacy in Poland and Ukraine: A Comparative Analysis

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Abstract: The paper focuses on surrogacy regulation, which is diverse across European countries. Four categories of rules can be identified, namely: absence of regulation, regulations allowing surrogacy, regulations that do not allow it with ongoing discussion about allowing it, and regulations under which surrogacy is strictly forbidden. Poland and Ukraine are neighboring countries with radically different regulations on surrogacy. There is no direct regulation on surrogacy in Poland and it can be stated that surrogacy agreements are not valid. IVF procedure is strictly forbidden for surrogacy. Ukraine is an example of the most liberal country when it comes to surrogacy regulation. Surrogacy agreements are regulated and requirements are formulated for surrogate mothers. Ukrainian regulation allows remuneration for surrogate mothers. After the Russian invasion, Ukrainian surrogate mothers came to Poland looking for safety. The Polish state provided extensive support for the Ukrainian people, including specific legal regulation on the right to access health care and employment opportunities. Yet, the Ukrainian surrogacy agreements are not valid in Poland, and the surrogate mothers will be approved as legal mothers.

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1. Introduction

Depending on biotechnological and social considerations, surrogate pregnancy can be classified based on various factors such as the origin of gametes and its onerous or altruistic character.[1]

When it comes to the first factor, five options are possible:

(1) A surrogate mother is only lending out her uterus to host an embryo which is transferred via in-vitro fertilization, but gametes (eggs and spermatozoids) are taken from a couple requesting the surrogate pregnancy;
(2) The egg belongs to the woman requesting surrogate pregnancy and the sperm comes from her partner or from a donor;
(3) The egg belongs to a surrogate mother who is fertilized by insemination with spermatozoids from the requesting male;
(4) The couple requesting the surrogate pregnancy has no biological link with the future child, with the embryo originating from donors or the surrogate mother;
(5) Three women are involved: one requesting surrogate pregnancy, one being the egg donor, and one who receives, hosts, and gives birth to the baby, while the sperm comes from the husband of the first woman or from a donor.[2]

The classification based on financial considerations distinguishes two options. On these grounds surrogacy can be defined as:

(1) commercial (monetary compensation is provided for a surrogate mother from those requesting her services in order to compensate for the days she may be absent from work because of the pregnancy and/or a period after birth, and medical examinations to which she will be subjected)[3];
(2) altruistic (the surrogate mother gets involved on altruistic grounds. This situation usually occurs in cases where family ties or friendship

1 Aitziber Emaldi Cirion, "Surrogacy in Spain. Medical, Legal and Ethical Perspective," *International Physical Medicine & Rehabilitation Journal* 2, no. 7 (2022): 82–9.

2 Cirion, "Surrogacy," 82.

3 Ibid.; Maria-Jose Cabezudo Bajo, "Avances hacia una regulacion de la gestacion por sustitucion en Espana en base al modelo regulado en el Estado de California," *Law and the Human Genome Review,* no. 46 (2017): 61–122.

exists between the surrogate mother and the intended parents.[4] Some jurisdictions allow the intended parents to compensate the surrogate's mother expenses[5]).

The purpose of this paper is to analyze the legal status of the Ukrainian surrogate mothers and the children they give birth to on the territory of the Republic of Poland after Russia's invasion of Ukraine. The research covers the following issues: comparative legal analysis of Polish and Ukrainian legislation on surrogacy and, in the event of differences, the question of whether the Polish legislator has provided temporary solutions in response to the differences in regulations.

The key issue analyzed in the paper is a comparison of the legislative experience of Poland and Ukraine on the subject of surrogacy in the context of the legal solutions adopted in various European countries. Although the legislations considered in this text belong to neighboring countries, it turns out that the solutions adopted in those countries are fundamentally different. Furthermore, Russia's invasion of Ukraine, launched on February 24, 2022, triggered a large wave of migration of the Ukrainian population to the territory of the neighboring country. Poland faced a huge logistic challenge of admitting a large number of migrants in a very short time. The differences in domestic regulations, especially in the area of biomedical law, have raised many questions concerning the legal situation of Ukrainian women in Poland.

While domestic regulations have already been the subject of legal discourses by representatives of the legal professions of both countries, comparing the laws and relating them to the regulations adopted in selected European countries has not been the subject of analysis and discussion so far. Moreover, the legal situation of Ukrainian surrogate mothers giving birth in Poland has not yet been studied. Therefore, the considerations presented in this paper fill this gap and provide a response to current legal questions.

This research cannot be conducted without answering the question of the necessity of comparing the domestic legislations of Poland and

4 Cirion, "Surrogacy," 82; Bajo, "Avances," 46.

5 Roman Maydanyk and Kateryna Moskalenko, "Towards Creation of Unified Regulation on Surrogacy in Europe: Recent Trends and Future Perspectives," *Wiadomości Lekarskie* 73, no. 12 (2020): 2865–70.

Ukraine. As it was pointed out by Van Hoecke, since the end of the 19th century, comparative law has been seen as an instrument for improving domestic law and legal doctrine, a way of renovating the Exegetic School to the Civil Code. Now, for many legal scholars in Europe, comparative law is considered the necessary instrument in the process of harmonization of law among European Union member states.[6]

This analysis is divided into three parts. The first part covers the analysis of domestic regulations on surrogacy in selected European countries. It presents the problem of cross-border surrogacy and some examples of it that have occurred in recent years. The second part of the paper focuses on the Polish and Ukrainian domestic legislations on this subject matter. The third part focuses on the legal situation of Ukrainian surrogate mothers staying in Poland during pregnancy and childbirth; specifically, on the question whether the Polish legislator provided temporary solutions to address the differences in the regulations of both countries.

The following questions are crucial for the matter presented: Which of the women would be entered on the child's birth certificate as its mother – the genetic mother or the surrogate mother? Would the genetic parents be able to claim any "rights to the child" born of the surrogate mother in Poland? Furthermore, problems related to the Ukrainian surrogate mother's access to health services related to pregnancy and childbirth are raised in the article.

The main goal of the research, including legal research, is to collect and analyze facts and their interpretation to ascertain or refute existing information or to add new information to it. The following legal research methods can be distinguished: evolutive and evaluative, identificatory and impact studies, projective and predictive, collative, historical, and comparative.[7] According to the doctrine, there are six methodological tools distinguished in the comparative law: the functional method (looking at the current societal problem and how it is resolved in different jurisdictions; presenting similar or different roads and results), the analytical

6 Mark Van Hoecke, "Methodology of Comparative Legal Research," *Law and Method* (Dec 2015): 2, https://doi.org/10.5553/REM/.000010.

7 Khushal Vibhute and Filipos Aynalem, *Legal Research Methods. Teaching Material*, Justice and Legal System Research Institute (2009), 110, accessed March 3, 2024, https://chilot.wordpress.com/wp-content/uploads/2011/06/legal-research-methods.pdf.

method (analyzing different concepts and rules in different legal systems; considering what similarities and differences are detected), the structural method (focused on the legal framework or the elements reconstructed through an analytical approach), historical method (showing differences and similarities between legal systems and the extent in which they belong to a tradition or historical events), the law-in-context method (focused on the law's current societal context, e.g. psychological, economic, religious, cultural).[8]

The presented considerations are based on the following research methods: collative method and comparative method (analytical and functional methods). The comparative legal method was used to analyze the national legislations of Poland, Ukraine, and selected European countries.

2. Surrogacy in Selected European Countries

Analyzing the legal regulations on surrogacy in European countries, one can notice their considerable diversity.[9] For instance, surrogacy regulation in European countries may fall within four categories: (1) no regulation for surrogacy is provided, however in practice surrogacy contracts are signed and enforced; (2) surrogacy is not allowed, however, the discussion on allowing it in the future is taking place; (3) surrogacy is allowed, and there are regulations on surrogacy; (4) surrogacy is strictly forbidden by the law.[10]

Almost all European countries prohibit any form of commercial surrogacy. Some of the countries have decided on regulations completely prohibiting the actions in question. France, Germany, Italy, and Spain have been chosen as examples illustrating the wide variety of regulations existing in Europe.

Article 16–7 of the French Civil Code states that "All agreements relating to procreation or gestation on account of a third party are void."[11]

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8 Van Hoecke, "Methodology," 28–9.

9 Valeria Piersanti et al., "Surrogacy and 'Procreative Tourism'. What Does the Future Hold from the Ethical and Legal Perspectives?," *Medicina* 57, no. 1 (2021): 47, https://doi.org/10.3390/medicina57010047.

10 Maydanyk, "Towards," 2865.

11 Available online: https://www.fd.ulisboa.pt/wp-content/uploads/2014/12/Codigo-Civil-Frances-French-Civil-Code-english-version.pdf, accessed March 3, 2024; more: Piersant, "Surrogacy," 47.

In Germany prohibition of surrogate motherhood is regulated by the Act for Protection of Embryos (The Embryo Protection Act). Section 1, paragraph 1, number 7 states that:

> Anyone will be punished with up to three years imprisonment or a fine, who attempts to carry out an artificial fertilisation of a woman who is prepared to give up her child permanently after birth (surrogate mother) or to transfer a human embryo into her.

However, paragraph 3, number 2 includes the exception, that "in the case of paragraph 1, number 7, the surrogate mother and likewise the person who wishes to take long-term care of the child, will not be punished."[12]

In Italy, according to Law 40 of 2004 on Assisted reproduction, surrogate motherhood is prohibited. What is more, all surrogacy contracts are void under the Italian Civil Code of 1942[13] and "the gamete donor does not acquire any legal parental relationship with the child and cannot claim any right or be the holder of obligations against him."[14] It is worth mentioning that recently in Italy there has been a heated discussion of a case involving a married couple, who, due to infertility problems (the woman had hysterectomy, while the man suffers from oligospermia), decided to turn to surrogate motherhood and heterologous insemination in a medical clinic in

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12 Available online: https://www.rki.de/SharedDocs/Gesetzestexte/Embryonenschutzgesetz_englisch.pdf?__blob=publicationFile, accessed March 3, 2024; more: Piersant, "Surrogacy," 47.

13 More: Andrea Boggio, "Italy Enacts New Law on Medically Assisted Reproduction," *Human Reproduction* 20, no. 5 (2005): 1153–7, https://doi.org/10.1093/humrep/deh871; Alfio Guido Grasso, "A Critical View on the Italian Ban of Surrogacy: Constitutional Limits and Altruistic Values," *The Italian Law Journal* 6, no. 2 (2020): 401–29.

14 Piersanti, "Surrogacy," 47; more: Gianluca Montanari Vergallo et al., "How the Legislation on Medically Assisted Procreation Has Evolved in Italy," *Medical Law* 36, no. 2 (2017): 5–28; Nicola Carone, Roberto Baiocco, and Vittorio Lingiardi, "Italian Gay Fathers' Experiences of Transnational Surrogacy and Their Relationship with the Surrogate Pre- And Post-birth," *Reproductive Biomedicine. Online* 34, no. 2 (2017): 181–90, https://doi.org/10.1016/j.rbmo.2016.10.010; Fabrizio Buonaiti Marongiu, "Recognition in Italy of Filiation Established Abroad by Surrogate Motherhood, between Transnational Continuity of Personal Status and Public Policy," *Cuadernos de Derecho Transnacional* 11, no. 2 (2019): 294–305, http://dx.doi.org/10.20318/cdt.2019.4959; Paola Frati et al., "Surrogate Motherhood: Where Italy Is Now and Where Europe Is Going? Can the Genetic Mother Be Considered the Legal Mother?," *Journal of Forensic and Legal Medicine*, no. 30 (2015): 4–8, https://doi.org/10.1016/j.jflm.2014.12.005.

Ukraine. As mentioned, such a solution violates the Italian law. As a result, on January 17, 2013, The Juvenile Court of Brescia, ordered the removal and adoption of a newborn baby.[15]

Surrogacy is also strictly prohibited in Spain. According to Article 10 of Human Assisted Reproductive Technologies Act[16]:

> 1. Any agreement whereby gestation is entrusted, with or without monetary consideration, to a woman who waives maternal parentage in favour of the other contracting party or a third party shall be null and void. 2. The parentage of children born by gestational surrogacy shall be determined by birth.[17]

3. Cross-Border Surrogacy – Ethical Dilemmas

According to the Report of the Special Rapporteur on the sale and sexual exploitation of children, including child prostitution, child pornography and other child sexual abuse material, commercial surrogacy ("for-profit" or "compensated" surrogacy) is focused

> on the contractual and transactional — rather than gratuitous — relationship between the intending parent(s) and the surrogate mother, (…) commercial surrogacy exists where the surrogate mother agrees to provide gestational services and/or to legally and physically transfer the child, in exchange for remuneration or other consideration.[18]

Prohibition of some form of surrogacy based on the origin of gametes and almost total prohibition of commercial surrogacy leads to so-called cross-border surrogacy or reproductive tourism. There are multiple reasons for this practice, such as avoiding restrictions arising from national jurisdictions or financial considerations. Most European countries, Israel, and many US states do not allow commercial surrogacy. The opening of the

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15 Ibid.

16 Ley 14/2006, de26 de mayo, sobre Técnicas de Reproducción Humana Asistida.

17 English translation from the Spanish Bioethics Committee Report on the Ethical and Legal Aspects of Surrogacy published in Carlos Martinez de Aguirre, "Surrogate Motherhood in Spanish and Latin American Law" the Law and the Loophole," in *Fundamental Legal Problems of Surrogate Motherhood. Global Perspective*, ed. Piotr Mostowik (Warsaw: Wydawnictwo Instytutu Wymiaru Sprawiedliwości, 2019), 367–97.

18 Human Rights Council, 37. Session, Agenda item 3, United Nations A/HRC/37/60, p. 11.

borders and domestic legislations enabling commercial surrogacy has resulted in the emergence of cross-border surrogacy, which results in agreements worth hundreds of millions of dollars being concluded each year in countries such as Thailand, Russia, Georgia, and Ukraine.[19] The cost of the procedure in Ukraine ranges from 40,000 to 65,000 euros.[20] For comparison, the cost of commercial surrogacy in the US ranges from $100,000 to $250,000, while in other countries from $35,000 to $100,000.[21]

Cross-border surrogacy takes place, when the intending parents are the nationals of one (or two) country (-ies), while the surrogacy itself is happening in another country, where, usually, the surrogate mother resides.[22]

The United Nations Human Rights Council emphasizes that abusive practices in the context of surrogacy are well documented, mentioning the employment of surrogates from India and Thailand by convicted sex offenders, the employment of 11 surrogates by a Japanese millionaire to give birth to 16 children, and the abandonment of a surrogacy-born infant with a disability.[23] This part of the research will focus on ethical challenges in non-European countries to prove that the absence of precise regulations might cause international dilemmas.

A matter that has stirred up much debate about the safety of children born through surrogacy was the case of Baby Gammy. A married couple from Western Australia, 56-year-old David John Farnell and his wife Wendy used a broker in Thailand to engage a 21-year-old Pattharamon Janbua as a gestational carrier. Janbua became pregnant with twins. In the fourth month of pregnancy, tests showed that one of the twins (a boy) had Down's syndrome, so she was asked to terminate the pregnancy, to which she did not agree. The twins were born two months prematurely. Mr and Mrs

19 After: Leslie R. Schover, "Cross-Border Surrogacy: The Case of Baby Gammy Highlights the Need for Global Agreement on Protection for All Parties," *Fertility and Sterility* 102, no. 5 (2014): 1258–9.

20 Susanna Marinelli et al., "The Armed Conflict in Ukraine and the Risks of Inter-County Surrogacy: The Unsolved Dilemma," *European Review for Medical and Pharmacological Sciences* 26, no. 16 (2022): 5646–50.

21 After: Schover, "Cross-border," 1258–9.

22 Maydanyk, "Towards," 2866.

23 Report of the Special Rapporteur on the sale and sexual exploitation of children including child prostitution, child pornography and other child sexual abuse material, Human Rights Council 37th session, General Assembly A/HRC/37/60, p. 9.

Farnell returned to Australia with a female twin, leaving Gammy, a seriously ill baby boy, with Ms. Janbua, who declared that she would raise him as her own son. The case gained considerable publicity when the twins were six months old and Ms Janbua was unable to cover the boy's medical expenses. It also turned out that the genetic father of the twins has been jailed twice over a 10-year period on more than 20 child abuse charges.[24] Pattharamon Janbua initiated legal proceedings to gain custody of Pipah (Gammy's twin sister) because she did not want the girl to stay with her father. In the opinion of Judge Stephen Thackray, the girl should have stayed with the Farnell family, however, safety measures were taken by the Child Protection Service to prohibit David Farnell from staying with the child by himself. The judge pointed out that the Farnells took some steps to take both children, but they thought that it had been Pattharamon Janbua who had decided to keep Gammy.[25]

Another case that aroused much discussion was the case of Mitsutoki Shigeta ("baby-factory" case), a 24-year-old multimillionaire from Japan who became the father of 16 children born to surrogate mothers living in Thailand. In 2014, Mr. Shigeta was investigated by Interpol for human trafficking. After leaving Thailand he sued the Ministry of Social Development and Human Security to obtain custody of the children. In 2015, he was granted custody of three children and in 2018 he obtained custody of another 13 children. Bangkok's Central Juvenile Court said that "for the happiness and opportunities which the 13 children will receive from their biological father, who does not have a history of bad behaviour, the court rules that all 13 born from surrogacy to be legal children of the plaintiff."[26]

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24 Schover, "Cross-border," 1258–9.

25 "Surrogacy: Pipah, Gammy's twin sister, will stay with her intended father who has a criminal record," Genethique, May 2, 2016, accessed March 3, 2024, https://www.genethique.org/surrogacy-pipah-gammys-twin-sister-will-stay-with-her-intended-father-who-has-a-criminal-record/?lang=en.

26 See more: "Mitsutoki Shigeta: 'Baby factory' dad wins paternity rights," BBC, February 20, 2018, accessed March 3, 2024, https://www.bbc.com/news/world-asia-43123658; Flora Carr, "Japanese Man Granted Sole Custody of 13 Children He Fathered With Thai Surrogate Mothers," Time, February 20, 2018, accessed March 3, 2024, https://time.com/5166372/japan-thailand-surrogate-children-custody/.

Mitsutoki Shigeta's case led to the enactment of the Protection for Children Born through Assisted Reproductive Technologies Act.[27]

4. Surrogacy in Ukraine

Ukraine's legislation on surrogacy is considered to be liberal and rather fragmented. There were a few draft laws on assisted human reproduction submitted to the Ukrainian parliament at the end of 2021 and during 2022–2023.[28] None of these draft laws passed the appropriate legislative procedure in the parliament. Surrogacy issues and relations are mostly regulated by special agreements between parties, which can have a number of variations. Also, the country allows (1) surrogate mothers to receive financial benefits in exchange for services compliant with the law[29]; (2) foreign nationals to enter into a surrogacy arrangement.

The core legal acts regulating the institution of surrogacy in Ukraine include the Civil Code of Ukraine, the Family Code of Ukraine, the Law of Ukraine Fundamentals of Healthcare legislation in Ukraine, the Order of the Ministry of Health No. 787 Procedure for the use of assisted reproductive technologies in Ukraine (with amendments), the Decree of the Ministry of Justice of Ukraine No. 52/5 dated October 18, 2000 (with amendments), Rules of State Registration of Civil Status Acts in Ukraine.[30]

The Civil Code of Ukraine provides for the right of an adult woman or man, based on medical indications, to undergo treatment programs using assisted reproductive technologies in accordance with the procedure and conditions established by law (Article 281(7)). Also, an adult capable

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27 Alessandro Stasi, "Protection for Children Born Through Assisted Reproductive Technologies Act, B.E. 2558: The Changing Profile of Surrogacy in Thailand," *Clinical Medicine Insights: Reproductive Health*, no. 11 (2017): 1179558117749603, https://doi.org/10.1177%2F1179558117749603.

28 Kateryna Moskalenko, "The Legal Framework on Surrogacy in Ukraine: Quo Vadis?," *International Comparative Jurisprdence* 9, no. 2 (2023): 209–25.

29 After: O.L. Kuchma and L.M. Siniova, "Surohatne materynstvo yak sposib realizatsii demohrafichnoi funktsii prava sotsialnoho zabezpechennia" ["Surrogate Motherhood as a Way of Implementing the Demographic Function of Social Security Law"], *Comparative Analytical Law*, no. 3 (2019): 108–11, quoted by Oleg M. Reznik and Yuliia M. Yakushchenko, "Legal Consideration Surrounding Surrogacy in Ukraine," *Wiadomości Lekarskie* 73, no. 5 (2020): 1048–52, http://dx.doi.org/10.36740/WLek202005139.

30 Reznik, "Legal," 1049.

person has the right to be a donor of, among others, reproductive cells (Article 290(1)). The Civil Code of Ukraine lays down the foundations of reproductive rights. More detailed regulations are contained in special legislation. At the same time, relationships in the sphere of surrogacy are regulated by contracts. The Civil Code of Ukraine does not directly provide for a contract that would outline the legal features of surrogacy relationships, however, taking into account the principle of freedom of contract, it has the right to exist, provided that it complies with the general principles of civil legislation.

Surrogate motherhood is also regulated by contracts. Usually, such contract(s) involve the following parties: intended parents, surrogate mothers, clinics specializing in reproductive medicine, and agencies. The contract between the intended parents and the surrogate mother defines their rights and obligations taking into account considerations of both the spouses and the surrogate mother. As the law contains only general requirements, the parties can include and specify different aspects of the contract, such as the medical aspects (medical examination during pregnancy, amount of medical assistance that will be provided during pregnancy, healthy lifestyle, etc.), economic aspects (compensation for services provided to the surrogate mother and/or financial costs associated with carrying and giving birth to a child), and organizational aspects (the clinic which will perform the procedure, monitor the pregnancy, and provide care at childbirth).

The Family Code of Ukraine regulates establishing the origin of a child born as a result of the use of assisted reproductive technologies (Article 123(2,3)). There are two specific regulations: (1) If a human embryo conceived by the spouses (husband and wife) using assisted reproductive technologies, is implanted in another woman, the spouses shall be the parents of the child (part 2 of Article 123 of the Family Code of Ukraine). (2) The spouses are recognized as parents of the child, which had been delivered by the wife after transferring into her body a human embryo, conceived by the husband and another woman as a result of using assisted reproductive technologies (part 3 of Article 123 of the Family Code of Ukraine). Such strict regulation protects the interests of the child's parents (specifically, the persons who decided to use surrogacy). The clause therefore makes the surrogacy contract enforceable, although it restricts access to surrogacy to married heterosexual couples: the legal registration of the

child reflects the surrogacy agreement signed by the intended parents and the consent in writing by the surrogate.[31]

The Fundamentals of Healthcare legislation in Ukraine stipulates that the use of artificial insemination and embryo implantation is carried out in accordance with the conditions and procedure established by the Ministry of Health of Ukraine, according to the medical indications of an adult woman with whom such an operation is performed, subject to the written consent of the spouses, ensuring the anonymity of the donor and preservation of medical confidentiality (Article 48).

The procedure for the use of assisted reproductive technologies in Ukraine has a special section (VI. Surrogacy) dedicated to surrogacy. This section defines general requirements for surrogacy, medical indications, organizational, and legal issues. The provisions concerning the determination of the child's origin and state registration are the following: in the case of the birth of a child by a woman in whose body a human embryo conceived by a spouse as a result of the use of ART was transferred (surrogate mother), the state registration of the child's birth is carried out at the request of the couple who gave consent to such a transfer (intended parents). In this case, simultaneously with the document confirming the fact of the birth of the child by this woman (surrogate mother), a statement is submitted about her consent (approved by a notary) to register the couple (intended parents) as the child's parents. A certificate of the genetic relationship between the couple (mother or father) with the fetus is also submitted. An identical provision is made in the Rules of State Registration of Civil Status Acts in Ukraine.

In the "Notes" section of childbirth registration records, the following information is included: "According to the medical birth certificate, the child's mother is a citizen (surname, first name, patronymic)." (namely – information about surrogate mother). In addition, the name of the institution that issued the certificate, the date and number of its issue, the notary's data (surname and initials, notary district or state notary office), the date, as well as the registration number under which the authenticity of the woman's signature was certified on the statement of her consent to register the couple as the child's parents. The record about the surrogate mother is made

[31] Marinelli, "The Armed," 5647.

precisely in childbirth registration records, and there is no such notice in the birth certificate. The birth certificate contains information about the biological parents only. This approach is adopted in order to protect the secrecy of birth using the method of surrogacy.

5. Surrogacy in Poland

According to The Family and Guardianship Code, the mother of a child is the woman who gave birth to it (Article 61^9).

Even though Polish legislation contains no provisions directly regulating the issue of surrogacy, representatives of legal doctrine agree that surrogacy contracts should be considered void.[32] In principle, the contract in question obliges the surrogate mother to consent to the implantation of the embryo, the delivery of the pregnancy, the birth of the child, and the relinquishment of parental rights to the child and the designation of the other party of the agreement as adoptive parents, while the other contracting party is obliged to take the child into care. According to Polish law, the provisions of the contract both requiring the child to be relinquished as well as releasing it to the genetic parents are void.[33]

As already mentioned, the provisions of the surrogacy agreement would be void of legal effects in Poland. At this point, however, it is worth answering the question whether any actions taken by potential adoptive parents and a surrogate mother would be legal in the Republic of Poland or would each one of them constitute a prohibited act? The analysis of this issue will be conducted in three stages. Firstly, the answer to the question of whether, under the current legal state, the application of Assisted Reproductive Technologies (ART) to fertilize a surrogate mother is possible, will be provided. Secondly, a criminal law analysis of activities aimed at giving birth to a child by a surrogate mother will be undertaken. Thirdly, it will be considered whether the institution of "adoption with indication," regulated

[32] Marek Andrzej Lebensztejn, "Macierzyństwo zastępcze – problemy etyczne i prawne," *Miscellaneas Historico-Iuridica* 13, no. 2 (2014): 308; Marek Safjan, *Prawo wobec ingerencji w naturę ludzkiej prokreacji* (Warsaw: Uniwersytet Warszawski. Wydział Prawa i Administracji, 1990), 436; Mirosław Nestorowicz, *Prawo medyczne* (Toruń: Towarzystwo Naukowe Organizacji i Kierownictwa „Dom Organizatora", 2005), 218.

[33] Krzysztof Pietrzykowski, *Kodeks rodzinny i opiekuńczy. Komentarz* (Warsaw: C.H. Beck, 2012), 639; Lebensztejn, "Macierzyństwo," 308.

by Article 119[1a] of The Family and Guardianship Code, can be applied to a child born by a surrogate mother.

The procedure of Assisted Reproductive Technologies (ART) is regulated in the Act of 25 June 2015 on the treatment of infertility (The Act of Infertility Treatment) and defined as "actions leading to the acquisition and use of germ cells or embryos inside or outside the body of the recipient for the purpose of procreation; it covers the direct and non-direct use of germ cells and embryos" (Article 2(1)(21)). The Polish legislator has provided for the application of Assisted Reproductive Technologies (ART) in two, differently conditioned, circumstances; namely, partner donation and non-partner donation. The first involves the donation of germ cells by a male donor for the purpose of using them in Assisted Reproductive Technologies (ART) in the body of the recipient who is married to the donor or in cohabitation with him confirmed by a mutual declaration of the donor and the recipient; in partner donation, the recipient's germ cells are used (Article 2(1)(8)).[34] Due to the requirement for the donor of male

[34] According to Article 29(1) the germ cells may be collected from a donor for partner donation only if all the following conditions are met: (1) the medical reasonableness of taking germ cells from a specific donor and using them for partner donation is determined by the doctor on the basis of the current state of medical knowledge; (2) based on the medical interview conducted with the donor candidate and the necessary medical and laboratory tests, it was concluded that: (a) the risk associated with collecting germ cells from a specific donor does not exceed the permissible limits for such treatments and will not significantly impair the donor's health, (b) it is possible to reduce the risk of a relevant adverse event or a relevant adverse reaction in the donor, the recipient and in children who may be born as a result of the use of these germ cells in the Assisted Reproductive Technologies; (3) before giving his consent a candidate for a donor: (a) has been informed in an understandable and detailed manner, by a person prepared for this purpose, about the type of the procedure, its purpose and nature, the laboratory tests carried out for its performance and the right to obtain the results of these tests, the way in which his personal data are collected and protected, medical confidentiality, the risks associated with the procedure of collecting the germ cells, the foreseeable consequences for his health in the future, the security measures leading to the protection of the donor's data and the scope and legal consequences of the use of the germ cells taken from him for the purpose of partner donation resulting from the provisions of the Act of 25 February 1964 – Family and Guardianship Code, including the legal situation of a child born as a result of the Assisted Reproductive Technologies, (b) has been given the opportunity to ask questions on the matters referred to in point (a) and receive comprehensive answers – which the candidate has confirmed by a written declaration; (4) the donor candidate has confirmed by submitting a written declaration that all information provided by him during the medical interview is true to the best of his knowledge; (5) the donor

germ cells and the recipient to be married[35] or in cohabitation, partner donation cannot be used for the purposes of surrogacy. The second type of donation occurs when there is no relationship between the germ cell donor or donors and the recipient. Without an in-depth analysis of the law in question, the wrong assumption that this type of donation would apply to surrogacy could be made. However, a reconstruction of the legal standard included in Article 20(1) of the Infertility Treatment Act indicates that donation other than partner donation is possible only if the recipient is married or in cohabitation with a man, because a necessary condition for the implantation of the embryo is the written consent of both the recipient and her husband (a consent to embryo transfer) or the man who is in cohabitation with her (acknowledgement of paternity by means of the Assisted Reproductive Technologies[36]). It can therefore be demonstrated that the Polish legislator has not provided for the possibility of the Assisted Reproductive Technologies (ART) being accessed by a single person,[37]

candidate has full legal capacity to perform legal acts and has voluntarily consented, in writing, before a doctor to the collection of germ cells and using them for partner donation; (6) the recipient, prior to giving her consent, has been provided with the information regulated by the Act; (7) the recipient has full legal capacity to perform legal acts and has voluntarily consented, in writing, before a doctor to use of donor's germ cells in her body or to use them in the Assisted Reproductive Technologies.

35 It should be noted that in Poland marriage is the union of a man and a woman, which can be concluded before the head of the Register Office or a cleric. Same-sex unions are not subject to legal regulation.

36 According to Article 751(1) of the Family and Guardianship Code the acknowledgement of paternity (AOP) takes place from the date of birth of the child, even then, when, prior to the transfer into the woman's body of the germ cells originated from an anonymous donor or an embryo created from germ cells from an anonymous donor or from donation of an embryo, a man declares before the head of the Register Office that he will be the father of a child who will be born following the Assisted Reproductive Technologies using those cells or that embryo, and the woman, at the same time or within three months from the date of the man's declaration, confirms that the man will be the father of the child. The declaration in question would be effective only if the child is born via ART within two years of submitting the declaration.

37 The legislation being in force since 2015 not only excluded the use of the Assisted Reproductive Technologies by single persons, but also resolved the legal situation of single women who had participated in such procedure before this Act entered into force. Embryos created in this way cannot be implemented into the body of a single woman, and 20 years after the Act entered into force, they should be transferred to so-called embryo donation. See: Rafał Łukasiewicz, "Implementacja zarodków utworzonych z komórek rozrodczych samotnych

a person remaining in a durable partnership with a person of the same sex, and a woman planning to become a surrogate mother. The considerations in question lead to the conclusion that it is impossible to use Assisted Reproductive Technologies (ART) in surrogacy.

It is also worth pointing out that behaviors violating the provisions of the analyzed Act are penalized. This is regulated in Article 78(1). The subject matter of the crime specified therein covers the use and transfer of germ cells taken from the donor, transfer of embryos into the recipient's body, and storage of embryos which have not been used in an Assisted Reproductive Technologies (ART) – the ones not being in accordance with the regulated procedure.[38]

To conclude, the Polish legislator not only ruled out the possibility of using Assisted Reproductive Technologies (ART) for the purpose of surrogacy, but also provided for criminal liability (fine, penalty of restriction of liberty, or imprisonment up to one year) for the actions in question.

As already mentioned, it would not be possible to use IVF for surrogacy in Poland, however, this does not imply that potential parents and surrogate mothers could not access the procedure in another country where it is permitted. Domestic legislation also does not prohibit the use of the natural conception by a surrogate mother and a genetic father, whilst assuming that a potential surrogacy agreement would be void of legal effects. While practice indicates that such a method is not used, it is worth considering how the legal status of the biological and genetic father would develop in such a hypothetical situation in both of the above cases. For one thing, it is possible to recognize both a child already conceived, in accordance with Article 75(1) of The Family and Guardianship Code,[39] and a child after the

kobiet – propozycje przepisów przejściowych," *Ruch Prawniczy, Ekonomiczny i Socjologiczny* 83, no. 1 (2021): 74.

38 See: Katarzyna Nazar, "Aspekty prawne procedur medycznych w zakresie postępowania z komórkami rozrodczymi i zarodkami w kontekście art. 78 ustawy z dnia 25 czerwca 2015 r. o leczeniu niepłodności," *Prokuratura i Prawo*, no. 10 (2021): 46.

39 An interesting issue, although beyond the scope of this discussion, is the question of the discrepancy between terminology used in various legal acts – the child already conceived and the conceived child. The first term was used by the Polish legislator when enacting that it could be an heir (Article 927(2) of the Civil Code) and it is possible to acknowledge paternity before the birth of a "child already conceived" (Article 75(1) of The Family and Guardianship Code). Whereas the term "conceived child" occurs i.e. in Criminal Code (aggravated crimes

delivery (Article 75(1) of The Family and Guardianship Code). In both circumstances, the legislator requires the declaration from the man from whom the child originates and, at the same time or within three months, from the child's mother, submitted to the head of the Registry Office.[40] The legislation in question does not require genetic tests to confirm the veracity of the declaration in question, but the head of the Registry Office is obliged to refuse the acknowledgement of paternity (AOP) if it is inadmissible or if he has any doubts as to the origin of the child (Article 73(3) of The Family and Guardianship Code). The issue is different in the case of a request for rescission of the parentage of a child submitted by the man who recognized the child and the child's mother – neither of them has the right to rescission of parentage on the grounds that the man is not the child's actual father. The only option provided by the Act is the defect of the applicant's statement of intent.[41] According to Polish jurisprudence, the recognition of the child is declaratory and works retroactively, which results from its declaratory nature. The *ex tunc* effects of it extend only to the family-law relationship between the recognizer and the recognized.[42]

Secondly, the so-called adoption with indication[43] (Article 119[1a] of the Family and Guardianship Code) is possible, which allows the parents to

of terminating pregnancy: with woman's consent – Article 152(3) and without her consent – Article 153(2), non-conviction clause for the conceived child's mother, who caused bodily harm to a conceived child or its health disorder threatening of its life – Article 157a(3)) and in Medical and Dentist Profession Act of 5 December 1996 (participating in the therapeutic experiment of a pregnant women requires a particularly thorough assessment of the associated risks for the mother and conceived child – Article 26 section 1). See: Filip Ciepły, "Prawne określenia człowieka w prenatalnej fazie rozwoju," *Ius novum* 9, no. 4 (2015): 79–82.

40 The declaration in question could also be submitted outside the territory of Republic of Poland to the Polish consul or a person designated to perform his/her functions, if at least one of the parents is a Polish citizen (Article 75§1 of The Family and Guardianship Code).

41 See: Polish Supreme Court, Judgment of 8 December 1972, Ref. No. I CR 353/72.

42 Provincial Administrative Court in Warsaw, Judgment of 13 May 2004, Ref. No. II SA/Wa 77/04.

43 According to Article 119[1a] Polish Family and Guardianship Code, the parents may, before the guardianship court, indicate the adopter, who may be exclusively the relative of the parents of the child with the consent of that person lodged before that court. The spouse of one of the parents may also be indicated. The institution of the designation of an adopter (adoption with indication) has been in force since September 18, 2015. Prior regulation allowed natural parents to indicate the adopter without limiting the category of persons. The amendment of the Act was primarily aimed at the reducing of so-called adoption underground and at

nominate the adopter, who can only be a relative of the child's parents with his/her consent, which was given to the court, or the spouse of one of the parents. Therefore, if there is a kinship between the surrogate mother and the future parents of the child, this institution could be used. Furthermore, acknowledgement of paternity makes it possible for the child to be adopted by the wife. Adoption with indication is an intrafamily adoption – it assures the parents that their child goes to a person they have designated and whom they know.[44]

To summarize the above considerations, it should be noted that the Polish law, while not providing for the validity of a surrogacy agreement, entails legal solutions that, in practice, could enable potential parents to obtain parental authority over a child born to a surrogate mother. The first situation would occur when the IVF takes place outside the Republic of Poland, and during pregnancy or after birth, the child is recognized by its father before the head of the Registry Office. The second situation would be the case of a relationship between the surrogate mother and one of the sociological parents, in which case a so-called adoption with indication would be possible. The third, and the only one that does not require the use of Assisted Reproductive Technologies (ART) outside the territory of the Republic of Poland, is when conception occurs naturally.

6. Legal Status of Ukrainian Surrogate Mothers Residing in the Territory of the Republic of Poland after the Russian Invasion of Ukraine

Another problem to be addressed by this analysis is the issue of the legal situation of Ukrainian surrogate mothers who, due to the armed conflict taking place in their country, gave birth on the territory of the Republic of Poland. Two questions arise in this context; namely, which woman would be

introducing statutory terminology of adoption with indication, which: would allow to maintain the full adoption as the basic form of adoption; would convince that a child from a particular family should remain in that very family; would prevent the transfer of children to adoptive persons for a fee and would protect children from being raised up by people without the appropriate qualifications and personal or moral aptitude. After: Anna Chciałowska, "Adopcja ze wskazaniem zgodnie z nowym uregulowaniem prawnym," *Zeszyty Prawnicze* 18, no. 4 (2018): 92.

44 Ibid., 89–107; Ewa Płonka, *Przysposobienie całkowite w prawie polskim* (Wrocław: Wydawnictwo Uniwersytetu Wrocławskiego, 1986), 97–8.

entered on the child's birth certificate as its mother – the surrogate or the genetic mother; and whether the Polish legislator has provided for regulations different from those that are in force for Polish citizens?

Before proceeding with the analysis, it is necessary to explain why the situation of Ukrainian surrogate mothers giving birth in Poland requires consideration at all. As stated above, Ukraine has the most liberal legislation on surrogacy. Global Families, a non-profit organization working with couples interested in surrogacy, reports that every year approximately 2,000–2,500 children are born in Ukraine through surrogacy, with at least 1,500 surrogate parent couples coming from the US, UK, Ireland, or Australia.[45] A report of the Warsaw Enterprise Institute, published in September 2023, entitled "Migration – Poland's missed (so far) opportunity" indicated that 2.5–3 million Ukrainians were probably staying in Poland. Analyzing data from the Border Guard, the authors of the report indicated that between February 24, 2022, and September 4, 2023, 15.2 million Ukrainians crossed the Polish-Ukrainian border, while 13.5 million Ukrainian citizens returned to their country.[46] It should be remarked here that since martial law was introduced in Ukraine, men cannot leave the country. We do not have data on how many pregnant Ukrainian women arrived in Poland after the war broke out. There is also no data on how many of the women are/were surrogate mothers.

7. Discussion

As already mentioned, after Russia's invasion of Ukraine, Poland faced a huge logistic challenge of admitting a large number of refugees and providing them with appropriate health and social care. In order to regulate the legal situation of Ukrainians, the legislator decided to introduce separate legislation for those who crossed the Polish border after the outbreak of

45 Priyanka Vora, "Russia's Invasion Is Damaging Ukraine's Booming Surrogacy Industry," Quartz, February 25, 2022, accessed September 9, 2023, https://qz.com/2133797/russias-invasion-is-damaging-ukraines-booming-surrogacy-industry.

46 Jarema Piekutowski, "Migracje: niewykorzystana (na razie) szansa Polski," Warsaw Enterprise Institute, September 2023, accessed September 11, 2023, https://wei.org.pl/wp-content/uploads/2023/09/Migracje-niewykorzystana-na-razie-szansa-Polski-raport.pdf.

the war.[47] From March 12, 2022, the Act on supporting Ukrainian citizens in connection with the armed conflict on the territory of this country has been in force.[48] The key issue regulated by the Act is defining the rules on obtaining and duration of legal residency in Poland. The Act does not apply to Ukrainian citizens who arrived on the Polish territory before the outbreak of the war, even if their arrival was due to warfare. Initially, the legal residency was to end after 18 months, but it has been extended until March 4, 2024.[49] The law in question allows Ukrainian citizens to access health services on the same terms that apply to persons covered by health insurance, with the exception of health resort treatment and resort rehabilitation (Article 37(1)). Therefore, answering the first question, it should be noted that the Polish legislator did not provide for a separate legislation aimed exclusively at pregnant women who are citizens of Ukraine. The Act does not mention surrogate mothers either.

It is crucial for the present analysis to establish which of the women would be entered on the child's birth certificate as its mother; the woman who gave birth to the child (surrogate mother) or the genetic mother?

As all relationships in the field of surrogacy are mostly regulated by contract(s), the place of birth of the future child is also indicated by the provisions of such contract(s). Should a surrogate mother remain in Ukraine to stay safe for herself and the baby? Should she seek refuge in a third country, such as Poland, Moldova, or Hungary, where parentage laws consign the intended parents to legal complications, or should she press on to a country such as the Czech Republic, where laws for parents are more accommodative?[50] Or should surrogate mothers even continue with their pregnancies?[51] Do surrogate mothers' contract obligations prioritize the

47 In the original wording, being in force until March 26, 2022, the legislation applied only to Ukrainians who came to Poland directly from the territory of Ukraine. The amendment was intended to extend the new arrangements also to persons who crossed the Polish border through another country.

48 Consolidated text: Journal of Laws 2003, item 103, as amended.

49 Amendment being in force since August 1, 2023.

50 Eszter Kismödi and Emma Pitchforth, "Sexual and Reproductive Health, Rights and Justice in the War against Ukraine 2022," *Sexual and Reproductive Health Matters* 30, no. 1 (2022): 1, https://doi.org/10.1080/26410397.2022.2052459.

51 André G. Dias Pereira, Radmyla Hrevtsova, and Thais N. Cesa e Silva, "Gestational Surrogacy: Legal Dilemmas and Experiences in Brazil, Portugal and Ukraine," *Global Health Law Journal* 1, no. 1 (2023): 15–40.

welfare of the unborn child? Surrogate mothers have clear obligations and are accountable to intended parents and, sometimes, agencies and clinics. On the other hand, however, the need to protect one's own and the unborn child's life and health should be recognized as a sufficient reason to flee to another region or country (in the case of our discussion, Poland). There are three possible scenarios here: (1) The surrogate mother moves to a safer region and gives birth to a child in a clinic in another region of Ukraine. In this case, there will not be any significant problems involved. Although the clinic that will accept the birth will change, the registration of the newborn child will be carried out according to the provisions of the Family Code of Ukraine and Rules of State Registration of Acts of Civil Status in Ukraine. (2) The surrogate mother will temporarily move to another country (Poland, for instance), but come back to Ukraine for the birth of the child. The result would be the same as in the first scenario. (3) The surrogate mother moves to Poland, and gives birth to the child in a Polish clinic. In this case, the registration of the newborn child will be carried out in accordance with the Polish Family and Guardianship Code.

As already mentioned, the provisions of the surrogacy agreement would be void of legal effects in Poland, and, under Polish law, the woman who gave birth to a child shall be deemed the mother of that child. The consequence of the above is indicating the adoptive mother as the child's legal mother and entering her data on the birth certificate. The Polish legislator has not provided separate regulations on this matter.

Based on the goals of this article, we offer one of the possible ways to address the situation of surrogate mothers from Ukraine, who have a child in Poland.

In 1993, Poland and Ukraine signed the Bilateral Agreement between the Republic of Poland and Ukraine on legal assistance and legal relations in civil and criminal matters.[52] This Agreement has section II "Family Law issues." Article 28(2) stipulates that "Establishing and disputing the origin of a child from a certain person is governed by the legislation of the

[52] Agreement between the Republic of Poland and Ukraine on legal assistance and legal relations in civil and criminal matters, accessed March 3, 2024, https://treaties.un.org/Pages/showDetails.aspx?objid=08000002805c4784.

Contracting Party whose citizen is the child's mother at the time of the child's birth."

Despite the generality of this provision, it is obvious that the legislation of the surrogate mother should be the legislation of Ukraine, namely, the provisions of Article 123 of the Family Code of Ukraine, where the intended parents must be recognized as parents.

8. Conclusion

In conclusion, it should be stated that surrogacy is an important issue that requires regulation at the national level. In the paper, it was demonstrated that selected countries chose different approaches to the matter; ranging from regulations forbidding surrogacy to liberal laws providing for regulated agreements with financial compensation.

The ethical dilemmas presented in the paper proved that the absence of safety regulation leads to a lack of safety for surrogate mothers and their children, which cannot be accepted in the modern democratic state of law.

Although Poland and Ukraine are neighbors, they chose opposite regulatory approaches to surrogacy. Poland has no direct regulation, but in the Family Code it is stated that the mother is the woman who delivered a baby. Surrogacy agreements are not legally binding. Ukraine, in contrast, is known as the most liberal country, where surrogacy agreements are regulated, and surrogate mothers can receive remuneration.

The differences in regulation in Poland and Ukraine were not a practical problem before the Russian invasion. However, the new situation in which Ukrainian surrogates came to Poland looking for a safe place showed that these issues should be discussed again. Unfortunately, it should be emphasized that the Polish legislators did not provide the necessary legal protection to Ukrainian surrogate mothers. What is more, no jurisprudential action was taken in this regard.

Despite the ongoing war, surrogacy is still practiced in Ukraine. Intended parents, surrogate mothers, agencies, and clinics have to make more complicated contracts. The lack of response from Polish authorities makes it necessary for surrogate mothers to seek shelter in countries with more favorable national regulations (Georgia and Cyprus become an option) to avoid complications that could arise from the Polish national regulation.

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EU Medical Device Regulation – The Level of Convergence and Impact on Regulatory Complexity

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Medical Device Regulation, Europeanization, EU convergence, multilevel governance, European administrative space

Abstract: The Medical Device Regulation (MDR) entered into force in 2017 and became applicable in 2021. In the context of Europeanization and the European Union (EU) multilevel governance system, regulations are used as a means of unification. The EU has gradually increased the degree of convergence in medical devices, even though medical devices pertain to the health sector, which is within the Member States' competence. Despite MDR being a regulation, its preamble states that its aim is to harmonize rules for the placing on the market and use of medical devices on the EU market. This article analyzes the level of convergence introduced by the MDR and its impact on regulatory complexity. Our findings demonstrate that many relevant elements, such as mandatory CE marking, reached the level of unification, whereas some that are still to become legally effective, such as the European database on medical devices (EUDAMED), went further and reached the highest level – supranational and integral joint administrative capacities. Unlike the expected inverse correlation between EU convergence and regulatory complexity, our findings revealed that due to delays in bringing into effect certain unifying elements, de facto, MDR introduced additional constraints compared to the previous Medical Device Directive (MDD) framework. This leads to the main finding of this research, which is that the MDR convergence increase has led to a conflicting outcome – an increase in regulatory complexity.

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1. Introduction

The European Union (EU) is a *sui generis* entity comprising 27 Member States (MSs). The EU has no constitution or statute as the highest founding law. Instead, two treaties are considered the EU's constitutional acts: the Treaty on the European Union (TEU) and the Treaty on the Functioning of the European Union (TFEU).[1] These treaties play a pivotal role in the EU's multilevel governance structure and, among others, distribute competences between MSs and EU institutions. The aims set in the treaties are achieved through the EU's legal acts. According to Article 288 TFEU, the EU can adopt regulations, directives, decisions, recommendations, and opinions to exercise its competences.[2]

A regulation is a binding legislative act that must be applied in its entirety across the EU. A directive is a legislative act that sets out a goal that EU countries must achieve; however, each MS can devise its own laws to reach this goal.[3] In the context of the EU being a multilevel governance entity, regulations and directives provide a basis for unification and harmonization.[4] These processes are means of creating European Administrative Space, which could be defined as "a set of principles, standards, policies and rules that, as a predominately informal 'acquis', should target countries towards the Europeanization of values, principles, processes and norms through convergence, harmonization and unification."[5] Harmonization refers to the compatibility of the law, that is, of one country's legal system with a certain law or legal system of another entity; the EU achieves this by adopting directives.[6] On the other hand, unification is the process of creating legal norms by means of a single law and legal system in the EU. This is

1 Jacques Ziller, "The Nature of European Union Law," in *Tratado de Derecho de la Union Europea*, vol. 4, eds. José María Beneyto, Belén Becerril, and Jerónimo Maíllo (Madrid: Aranzadi, 2011), 1365.

2 European Union, *Consolidated versions of the Treaty on European Union and the Treaty on the functioning of the European Union – Charter of Fundamental Rights of the European Union*, Publications Office, 2010. Treaty on the Functioning of the European Union (TFEU), Article 288.

3 Ibid.

4 Vilim Bouček, *Europsko međunarodno privatno pravo u eurointegracijskom procesu i harmonizacija hrvatskog međunarodnog privatnog prava* (Zageb: Manualia Universitatis Studiorum Zagrebiensis, 2009), 9 – translated by the author.

5 Bruno Nikolić and Polonca Kovač, "The European Administrative Space between Ideals and Reality," in *The Science of Public Administration*, eds. Janez Stare and Mirko Pečarič (Ljubljana: Faculty of Public Administration, 2021), 622.

6 Bouček, *Europsko međunarodno privatno prawo*, 9.

achieved by adopting regulations.[7] Lately, there has been a noticeable trend towards more frequent use of a unification approach instead of harmonization of the EU law, which is reflected in the application of regulations by which the legislature repeals previously valid directives. Examples of these are visible in highly regulated sectors, such as construction, medical devices, automotive, personal protective equipment, beauty industry.[8] This leads towards an increase in EU convergence. The highest level of convergence should lead to the institutionalization of autonomous and independent joint administrative capacities at the EU level.[9]

This article examines two research questions regarding the EU being a multilevel governance entity. Firstly, it examines the level of Europeanization, i.e. EU convergence reached within the MDR framework. In its preamble, MDR states that its objective is to harmonize rules for placing medical devices on the market and putting them into service in the EU. However, the legislator has not used a directive to harmonize the regulations, as was previously done with the Medical Device Directive (MDD).[10] Instead, the legislator has employed a regulation, which is a unification tool. Based on a qualitative analysis, this research will examine relevant elements of medical device conformity and lifecycle management to determine the level of convergence of the MDR framework. Based on these findings, the article will further evaluate the relationship between convergence and regulatory complexity in medical devices. It will determine whether the presumed increase in convergence introduced by the MDR has led to a presumed decrease in regulatory complexity. Regulatory frameworks ensure that safety and effectiveness are being evaluated, while at the same time, they present barriers that can hold up innovative processes.[11] The literature review revealed a lack of research on regulatory complexity.[12] Recent research

7 Ibid., 10.

8 Nika Gavrilovic, *Europski pravni okvir za uređenje motornih vozila i analiza novosti koje donosi Uredba EU 2018/858 o homologaciji i nadzoru tržišta motornih vozila* (Zagreb: University of Zagreb, Faculty of Law, 2020), 5–6.

9 Nikolić and Kovač, "The European Administrative Space," 627.

10 EU(1993) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (O.J.E.C. L169, 12 June 1993).

11 Jeroen H.M. Bergmann, "The Emerging Field of Medical Regulatory Technology and Data Science," *Prosthesis* 4, no. 2 (2022): 170.

12 Ibid.

findings demonstrate a need for better metrics regarding regulatory complexity in general, defining complexity within regulations, and determining an appropriate level of regulatory complexity.[13] Despite limited research on regulatory complexity, we can indicate scientific publications which analyze this topic from different angles. Arnould, Hendricusdottir, and Bergmann measured regulatory complexity in terms of the readability of the text and demonstrated that the MDR regulatory complexity is higher than that of the MDD.[14] Whereas, de Lucio and Mora-Sanguinetti state that the concept of complexity refers to problems regarding the "form" rather than the specific topics covered by regulation and examine three dimensions of complexity: quantity (because the corpus is too broad), linguistic (because norms are ambiguously or poorly drafted), and relational (complexity deriving from how rules are connected to each other).[15] On the other hand, some researchers did not define regulatory complexity[16] or would use several terms that can add up to complexity or can be evaluated as independent elements, such as regulatory constraints, outlays, delays, and uncertainties.[17] This research defines regulatory complexity as the application of norms in an interdisciplinary environment under the existing legal system measured by human and financial resources invested into fulfilling a regulatory requirement. Regulatory complexity is higher when more resources and/or activities are necessary to conform to a regulatory requirement than before the introduction of regulatory changes. Regulatory complexity could be significant for evaluating the medical device framework's efficiency and effectiveness. Examples of regulatory complexity are administrative constraints or otherwise burdens, such as an MS's registration of a CE-marked medical device already placed and registered in another MS, repetition of

13 Ibid.

14 Arthur Arnould, Rita Hendricusdottir, and Jeroen Bergmann, "The Complexity of Medical Device Regulations Has Increased, as Assessed through Data-Driven Techniques," *Prosthesis* 4, no. 3 (2021): 318–30.

15 Juan de Lucio and Juan S. Mora-Sanguinetti, "Drafting 'Better Regulation': The Economic Cost of Regulatory Complexity," *Journal of Policy Modeling* 44, no. 1 (2022): 163–83.

16 Iraj Daizadeh, "The Impact of US Medical Product Regulatory Complexity on Innovation: Preliminary Evidence of Interdependence, Early Acceleration, and Subsequent Inversion," *Pharmaceutical Research* 40, no. 6 (2023): 1541–52.

17 Richard B. Stewart, "Regulation, Innovation, and Administrative Law: A Conceptual Framework," *California Law Review* 69, no. 5 (1981): 1283.

the same or analogous activities on several horizontal and vertical levels, such as report submission, etc.

The structure of this article is as follows. Part I evaluates levels of convergence of relevant MDR elements of medical device conformity and lifecycle management to determine the MDR framework's level of convergence. Both MDD and MDR elements will be examined.

Based on the findings from Part I, Part II places the MDR's convergence level in a relationship with regulatory complexity. In Part II, the article will evaluate whether a convergence increase leads to increased or decreased regulatory complexity in the medical device field.

2. Europeanization of the Medical Device Sector – From Competence Creep to Harmonization

To understand the convergence of the medical device framework, it is important to know the arena within which it has been built. In this article, medical device(s) are defined as medical technology and medical equipment, as per the definition of medical device from EU legislation based on the MDD[18] and MDR.[19]

Competence creep is a phenomenon whereby the EU somehow manages to legislate and/or otherwise act in areas where it has not been conferred a specific competence.[20] Competence creep is associated with the EU's broad interpretation of a certain legal provision.[21] This form of competence creep is primarily concerned with the positive intervention of the EU institutions, i.e. notably the exercise of legislative powers. However, the EU can also trigger other intervention methods. At the same time, one may also conceive competence creep in a broader sense, meaning that MSs must always comply with the EU law, although the competence lies with the MSs.[22] Health law and regulating medical devices are pioneering examples of this

18 See: MDD, Article 1.
19 See: MDR, Article 2.
20 Stephen Weatherill, "Competence Creep and Competence Control," *Yearbook of European Law* 23, no. 1 (2004): 5.
21 Ibid., 5–6.
22 Ibid.

phenomenon.[23] Based on TEU and TFEU, health is a sphere that falls within MS competence. In 1993, the Treaty of Maastricht introduced the first formal EU health competence. Article 129 EC (previously EEC) provided powers for the EU to contribute towards a high level of human health protection by encouraging cooperation between MSs and, if necessary, lending support to their action.[24] As correctly annotated by Hervey and de Ruijter, "prohibition on harmonization of national laws, in the legal text that attributes legislative powers to the EU, underlines the paradox that was part of the health competence from its inception."[25] Although there were significant amendments in 1999's Treaty of Amsterdam and 2007's Lisbon Treaty, which encompass obligations of the EU to ensure a high level of human health protection in all Union activities, it has been observed that

> the key constraints to the Union's competence provisions in health reiterate that there is no Union power to harmonise national law or policy in order to protect or improve human health, or directly to protect public health, however, Articles 2–6 TFEU describe at least 6 forms in which competence creep may take place, which all take place in areas where Member States have retained authority.[26]

We can trace the beginnings of EU regulation in the medical device sector as early as 1985. In 1985, the EU introduced a Council resolution on a new approach to technical harmonization and standards (New Approach Resolution).[27] The New Approach Resolution does not explicitly mention medical devices but provides a basis and guidelines for standardising and harmonising industrial products. The first step of the EU's harmonising activity in the sector took place in 1990, when the European Commission (EC) introduced the Active Implantable Medical Devices Directive (AIMDD),[28] while in 1993, the same year as the above-mentioned Treaty of Maastricht,

23 Tamara Hervey and Anniek de Ruijter, "The Dynamic Potential of European Union Health Law," *European Journal of Risk Regulation* 11, no. 4 (2020): 729.

24 Ibid., 728.

25 Ibid., 729.

26 Ibid., 728.

27 EU(1985) Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards (O.J.E.C. C136, 4 June 1985).

28 Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (O.J.E.C. L189, 20 July 1990).

enacted MDD. MDD's preamble references Article 100a EEC as the legal basis which obliges the EEC to issue directives to support the establishment and functioning of the Common Market. This change has *de jure* and de facto led to the harmonization of medical device legislation and standardization of the devices. AIMDD and MDD are New Approach Directives.[29]

Amendments to medical device legislation took place in several stages; in 1998, 2000, 2002, 2003 and 2007 for MDD,[30] and in 1993, 2003 and 2007 for AIMDD.[31] Meddev guidance documents (MEDDEVs) are the EC's official guidance for medical devices. The MEDDEVs promote a common approach to be followed by manufacturers and notified bodies (NB(s)) involved in conformity assessment procedures.[32] Several MEDDEVs were issued from 1994 to 2019.[33] For example, in 2004, Evaluation of medical devices incorporating products containing natural rubber latex;[34] in 2010, Classification of medical devices[35] and Guidelines on clinical investigation;[36] in 1998, for medical devices with a measuring function;[37] in 2012, Guideline for authorized representatives;[38] in 2013, Guidelines on a medical devices vigilance system;[39] in 2016, on qualification and classification of stand-alone software,[40] etc. Therefore, we agree with Hervey and de Ruijter

29 See: "The New Approach Directives includes a large number of Directives, whose common element is that they rely principally on self-certification through the application of the well-known CE-marking on compliant products," European Union Agency for Cybersecurity, accessed December 23, 2023, https://www.enisa.europa.eu/topics/risk-management/current-risk/laws-regulation/e-business/new-approach-directives.

30 Consolidated text: Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, accessed February 26, 2024, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01993L0042-20031120.

31 Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, accessed February 23, 2024, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31990L0385.

32 Guidance MEDDEVs, accessed February 23, 2024, https://health.ec.europa.eu/system/files/2022-01/md_guidance_meddevs_0.pdf.

33 Ibid.

34 MEDDEV 2.5/9 rev.1 Evaluation of medical devices incorporating products containing natural rubber latex, February 2004.

35 MEDDEV 2.4/1 rev.9 Classification of medical devices, June 2010.

36 MEDDEV 2.7/4, Guidelines on clinical investigations: a guide for manufacturers and notified bodies, December 2010.

37 MEDDEV 2.1/5 Medical devices with a measuring function, June 1998.

38 MEDDEV 2.5/10, Guideline for authorised representatives, January 2012.

39 MEDDEV 2.12/1 rev.8 Guidelines on a medical devices vigilance system, January 2013.

40 MEDDEV 2.1/6 Qualification and classification of stand alone software, July 2016.

that many harmonising measures were adopted in the EU's health law and policy through the 1990s, 2000s and 2010s.[41] MDR references TFEU's Article 114 on the free movement of goods and Article 168 (4)(c): "measures setting high standards of quality and safety for medicinal products and devices for medical use as the legal basis." The preamble further states that MDR's aim is to ensure the smooth functioning of the internal market for medical devices, taking as a base a high level of protection of health for patients and considering the small- and medium-sized enterprises, as well as setting high standards of quality and safety for medical devices. Both objectives are linked, and neither is secondary to the other. As regards Article 114 TFEU, MDR harmonizes the rules for placing on the market and putting into service in the EU single market, thus allowing them to benefit from the principle of free movement.[42] MDR entered into force in 2017 but became applicable in 2021. There have been three amendments to the MDR in April 2020,[43] December 2022,[44] and March 2023.[45] These amendments introduced changes such as changes to Article 120 (changes in deadlines concerning transitioning from MDD to MDR compliance and changes to sell-off provisions).[46]

41 Hervey and de Ruijter, "The Dynamic," 731. Moreover, the EU started working on the MDR in 2012, and the final text was adopted in 2017. Since then, more than 100 MDCG (Medical Device Coordination Group) guidance documents have been published.

42 MDR, Preamble.

43 Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions.

44 Commission Delegated Regulation (EU) 2023/502 of 1 December 2022 amending Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the frequency of complete re-assessments of notified bodies.

45 Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

46 Amendments: M1 Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 (O.J.E.C. L130, 24 April 2020, p. 18), M2 Commission Delegated Regulation (EU) 2023/502 of 1 December 2022 (O.J.E.C. L70, 8 March 2023, p. 1), M3 Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 (O.J.E.C. L80, 20 March 2023, p. 24). Corrections: C1 Corrigendum (O.J.E.C. L117, 3 May 2019, p. 9, 2017/745); C2 Corrigendum (O.J.E.C. L334, 27 December 2019, p. 165 (2017/745)).

Having a broader scope than the MDD, MDR addresses the entire lifecycle of a medical device. For example, increased requirements for clinical evaluation and investigations,[47] implementation of a system for identification and traceability of medical devices (the Unique Device Identification system (UDI)),[48] European database on medical devices (EUDAMED),[49] strengthening requirements for post-market surveillance and post-market clinical follow-up.[50]

3. Level of Convergence of the Medical Device Framework

This part of the article will analyse the level of convergence of relevant elements of medical device conformity and lifecycle management to determine MDR's level of convergence. The level of convergence will be assessed using a qualitative research method. MDD and MDR elements and the de facto state will be examined, as some MDR elements are not legally effective. Levels of Europeanization, i.e. the level of convergence, will be assessed against the methodology from Nikolić and Kovač presented in the Figure 1.[51]

MDR has been applicable since 2021, whereas some elements are still ineffective. For example, all devices except for class I devices[52] do not need to be compliant with the MDR but can remain on the market as MDD-compliant devices for a determined time under Article 120 MDR[53] and implementation and usability of EUDAMED platform.[54] In addition to delaying the legal effect of certain provisions, lack of clarity of some norms (such as device classification, economic operators' responsibilities, Unique Device Identification assignment, post-market surveillance and

47 See: MDR, Chapter 6.

48 Ibid., Article 27.

49 Ibid., Articles 30, 31, 33, 34.

50 Ibid., Chapter 7; Ann-Kathrin Carl and David Hochmann, "Impact of the New European Medical Device Regulation: A Two-Year Comparison," *Biomedical Engineering/Biomedizinische Technik* (2023), 1.

51 Nikolić and Kovač, "The European Administrative Space," 627.

52 In accordance with Article 51 MDR, medical devices are divided into the following classes: I, IIa, IIb and III, taking into account the intended purpose of the device and its risks. For more information on class I medical devices, see MDCG 2021–24 Guidance on classification of medical devices.

53 MDR, Article 120.

54 Ibid., Article 33.

	Subject of Europeanisation	Dimensions of Europeanisation	Levels of Europeanisation
1	Beliefs and values	Transition of principles common to most MS to the EU level	Convergence of objectives
2	Public governance processes through institutional cooperation	Formulation and implementation of overarching and sectoral public policies	Convergence in approaches (e.g. obligatory public participation) and harmonisation
3	Norms or legal coordination	Uniform principles of administrative law and common rules	Harmonisation (transposition of directives into national law) and unification (basic acts, EU regulations)
4	Institutions: a) sectoral, b) horizontal.	Integral European administration, through sectoral regulations and EU agencies to uniform actions (e.g. EU semester).	Supranational and integral PA, i.e. umbrella joint bodies in the EU and intensification of authorities (bodies) of the EU in multilevel governance

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Fig. 1. Degrees of Europeanization through subject, dimensions and gradual stages of development (Bruno Nikolić and Polonca Kovač, "The European Administrative Space between Ideals and Reality," in *The Science of Public Administration*, eds. Janez Stare and Mirko Pečarič (Ljubljana: Faculty of Public Administration, 2021), 627).

vigilance requirements, significant changes, conformity assessment procedures) presents additional issues. To mitigate these issues, EC-chaired groups were established to provide additional guidance for interim and long-term application of MDR. For example, the Medical Device Coordination Group (MDCG) and Notified Bodies Oversight (NBO).[55] As a result of the forum, guidance documents are often issued. These are important soft laws for administrators and industry stakeholders as they provide

[55] See: Medical Device Coordination Group Working Groups, accessed December 26, 2023, https://health.ec.europa.eu/medical-devices-dialogue-between-interested-parties/medical-device-coordination-group-working-groups_en.

clarification on specific subjects.[56] This research will also base its assessment on MDCG 2021–1 Rev.1 Guidance on harmonized administrative practices and alternative technical solutions until EUDAMED is fully functional (MDCG 2021–1). Some MDCG guidance documents, such as the MDCG 2021–1, provide interim rules that should govern the activities of stakeholders until all MDR elements are legally effective.

Selected elements of medical device conformity and lifecycle management that have been assessed concern CE marking, conformity assessment procedure, registrations, and reporting:

- CE marking is common for New Approach Directive products and was introduced by the MDD. It facilitates Europeanization based on the EU's free movement of goods. The product should be EU-compliant once it is CE-marked. Nonetheless, MSs may impose additional regulatory constraints depending on the product class.
- EUDAMED is introduced by Article 33 MDR. It contains six modules that should facilitate the collation and processing of information to register products and economic operators, UDIs, NBs, certificates, etc. Therefore, EUDAMED tackles several elements the legislator raised to the EU level.[57]

The elements were assessed and placed in the table 1 below based on Nikolić and Kovač scheme.

Table 1. Assessment of the convergence level of relevant medical device conformity and lifecycle management elements.

MDD	MDR, upon becoming entirely legally effective	Currently in practice, de facto state	Level of convergence
Element: Obtaining CE marking			
Through an NB, designated on the EU level. Therefore, MDD introduced unifying effects.	Through an NB, designated on the EU level.	All MDR provisions are currently legally effective in this respect.	Process for obtaining CE marking is the same in all MSs. We can conclude that this element is unified within the EU and that MDD has already achieved unification.

[56] See: MDR, Article 105, on the tasks of MDCG.

[57] MDCG 2021–1, p. 2.

MDD	MDR, upon becoming entirely legally effective	Currently in practice, de facto state	Level of convergence
Element: EC conformity assessment procedure for medical devices			
EC conformity assessment procedure is mandatory, except for allowing registration in the MS based on national justified derogation, as per Article 11 MDD. Therefore, MDD introduced harmonising effects for this element.	EC conformity assessment procedure is mandatory, except for allowing registration in the MS based on national justified derogation, as per Article 59 MDD.	All MDR provisions are currently legally effective in this respect.	EC conformity assessment procedure is mandatory, except for derogation cases where MSs may allow devices on their market based on national derogation. Therefore, we can conclude that this element is harmonized within the entire EU, which MDD has already achieved.
Element: Medical device registration at the MS level			
National registration in (each) MS that requires device registration is permissible under the national laws of MSs.	Once EUDAMED is effective, the national authority where the first registration takes place will relate to EUDAMED, and hence, that first registration will be transferred to the EU level, i.e. it will be applicable to the entire EU. Therefore, once EUDAMED is effective, only 1 registration will be needed for the entire EU. Before placing a device, the manufacturer, under the rules of the issuing entity referred to in Article 27(2), assigns a Basic UDI-DI as defined in Annex VI to the device and provides it to the UDI database together with the other core data elements referred to in Part B of Annex VI related to that device.	EUDAMED is expected to be implemented in 2029. According to MDCG 2021–1, the registration of devices starts to apply 24 months after the date of publication of the notice of full functionality of EUDAMED. Until then, both MDD and MDR devices will continue being registered on MS(s) level(s). See MDR preamble, paragraph 98. Moreover, as per Article 31(3) MDR, when applying to NBs for conformity assessment, manufacturers must use the SRN, which is obtained through EUDAMED.	As EUDAMED is still not effective, MSs may still require device registration. If there is a need for conformity assessment via NB, SRN must be obtained via EUDAMED. Therefore, we can conclude that this element is harmonized. Moreover, we can conclude that this element requires duplication of activities on vertical and horizontal levels: - Devices must be registered on the MS level; - SRN must be obtained through the applicable module on EUDAMED (EU level). Upon EUDAMED becoming effective, based on the current version of MDR, this element will reach the level of unification as EUDAMED will present supranational joint administrative capacities. Therefore, there will be no need for repetition of analogous activities.
Registration of manufacturers, authorized representatives, and importers			
Authorized representatives, EU manufacturers and importers must register with the competent authority of the MS. Non-EU manufacturers must be registered with the competent authority of their authorized representative. Therefore, MDD introduced harmonising effects for this element.	The competent authority of the MS obtains a single registration number (SRN) from the electronic system referred to in Article 30 and issues it to the manufacturer, the authorized representative, or the importer. SRN must be used when applying to an NB for conformity assessment and for accessing EUDAMED to fulfil other obligations.	As EUDAMED is not yet effective, MDD provisions referring to the MS provisions are applicable; see MDR preamble, paragraph 98.	This element has reached the level of harmonization. There is still a high degree of horizontal cooperation of multiple competent authorities. Upon EUDAMED becoming effective, based on the current version of MDR, this element will reach the final level of unification as EUDAMED will present supranational joint administrative capacities. There will be no need for repetition of analogous activities.

MDD	MDR, upon becoming entirely legally effective	Currently in practice, de facto state	Level of convergence
Element: Incident reporting			
Incident reporting goes through the manufacturer's NB. Therefore, MDD introduced harmonising effects for this element.	Incident reporting goes through EUDAMED to the manufacturer's NB.	MDD set-up is being applied in practice. In the interim, manufacturers and NBs are advised to agree on how that information is provided to the NB which issued the certificate for the device in question and may continue with the same procedures used under the MDD.	This element has reached a harmonising effect. Activities are coordinated by an NB and depend on the NB. Upon EUDAMED becoming effective, based on the current version of MDR, reports of serious incidents will be automatically transmitted to the NB that issued the certificate for the device in question through EUDAMED. Therefore, once EUDAMED is effective, this element will reach the final level of unification. There will be a decrease in the multiplication of analogous activities.
Element: vigilance (and post-market surveillance)			
MDD vigilance and post-market surveillance required notification of incidents to the MS competent authority. EC published guidance MEDDEV 2.12/1: Guidelines on a medical device vigilance system.[58] The latest was in 2019. Therefore, MDD introduced harmonising effects for this element.	Concepts of vigilance and post-market surveillance are divided. Reporting through EUDAMED.	Until EUDAMED is effective, reporting must be done to the MS competent authority.	In practice, activities must be notified to the MS competent authority. Upon EUDAMED becoming effective, vigilance reports will be submitted to EUDAMED instead of the MS competent authority of incidents. Therefore, once EUDAMED is effective, this element will reach the final level of unification. There will be a decrease in the multiplication of analogous activities.

We can conclude that MDD has already introduced Europeanization, i.e. EU convergence into the medical device field by providing a legal basis which converges MSs' beliefs, values, objectives, processes for MS cooperation and, finally, harmonized national legislative acts that regulate medical devices (see below Figure 2), as notated by Hervey and de Ruijter.[59] We can also conclude that MDD reached the third level of convergence, as per the Nikolić and Kovač table, where legal coordination and uniform principles of administrative law and common rules contribute to harmonization and unification.

[58] MEDDEV 2.12/1: Guidelines on a medical device vigilance system (MEDDEV 2.12/1, rev. 8).
[59] Hervey and de Ruijter, "The Dynamic," 731.

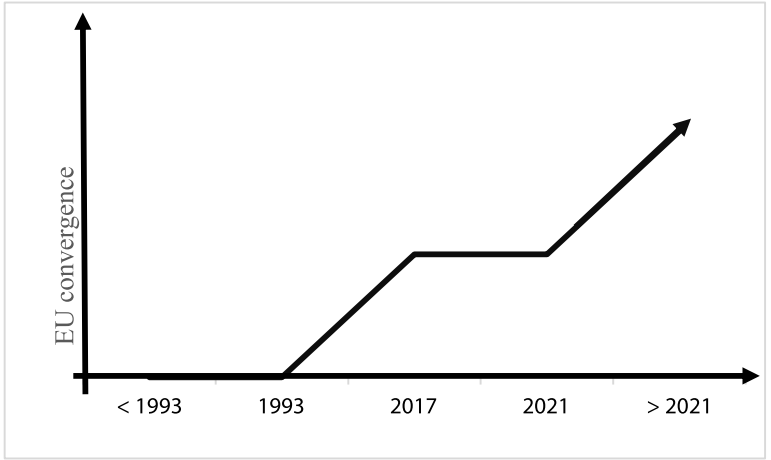

Fig. 2. EU convergence increase.

For example, several MEDDEVs were issued between 1994 and 2019. Since then, more than 100 MDCG guidance documents have been published. From 1993 until today, several public administration approaches contributed to the convergence:

- Normative – mandatory CE marking, MDR as the applicable, hard law, and soft laws being written by MDCG, NBO and other EC-chaired groups.
- Political – political agreement towards increasing EU convergence, demonstrated by continuous participation of MS representatives and MS-elected experts in the MDCG, NBO and other bodies.
- Cultural – healthcare, safety of patients, safety, efficiency, and availability of devices as the core values and objectives of MDD and MDR.
- Economical – willingness to create a basis for free circulation of CE-marked devices and eliminate MS provisions that constrain freedom of movement.

As observed in Table 1, MDR increased some elements to unification (registration of devices and economic operators; incident reporting,

vigilance, and post-marketing reporting). Despite MDD being in force for over 25 years and MDR being a unification tool regulation, our findings reveal that MDR reached its objective – harmonization. Regulation as a tool to (only) harmonize and not unify is noticeable in the EU's regulation of other products, such as Personal Protective Equipment Regulation[60] and Cosmetics Regulation.[61]

4. Relationship between the Level of Convergence and Regulatory Complexity in the Medical Device Framework

In 1993, MDD introduced mandatory CE marking of medical devices. On top of the CE compliance route, each MS can derogate from CE marking and any other MDD conformity rule. This is possible as health is an MS competence. MDR follows this logic. Regardless of it, CE marking a device is the only path for clearing the devices for their placement in the (entire) EU single market. This norm itself introduces a significant decrease in regulatory complexity, as it avoids national marking or other demonstration of conformance in each MS, as was the case before MDD. This significantly decreases administrative burdens and, therefore, regulatory complexity, which is in line with our presumption that increasing convergence decreases regulatory complexity.

Despite this, some MSs still require registration of devices on the MS level, such as Italy, Spain, Portugal, Croatia, Greece, etc. This presents a direct obstacle to the free movement of medical device goods, as per Article 26 TFEU. In line with our definition, this can be considered as regulatory complexity. EUDAMED will eliminate this constraint, as registration will be transferred to the EU level, i.e. to EUDAMED, as soon as registration in the first MS occurs. This will significantly decrease regulatory complexity, as stakeholders will not have to register and re-register devices in every MS whenever there is a significant change to a device

60 Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC, see Preamble, paragraph 1.

61 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, see Preamble, paragraph 1(4).

or economic operators.[62] The MS registration elements are still applied in practice as EUDAMED legal effectiveness has been postponed to approximately 2029.[63] While because of EUDAMED postponement, certain MDD harmonising elements remain effective, such as national registration, the industry is already applying certain MDR elements in parallel, e.g. UDI and SRN, which require one to register (through already available modules) on EUDAMED.[64] Therefore, we can conclude that stakeholders must perform the same or similar activities on both MS and EU levels. Some activities, such as national registration, must be repeated in several MSs. This leads to increased regulatory complexity and is an obstacle to the free movement of devices within the EU.

Figure 3 shows that increasing convergence is a general direction of EU policymakers and legislators. However, we observe that MS public administrations are not ready to concede their national registration system or implement unification tools. Within currently applicable legislation and under the EU public policy, there are many obstacles that public administrators should tackle to bring MDR into practical application, namely, to facilitate EUDAMED.

Our findings further demonstrate that several elements of MDR, such as economic operator and product registration, incident reporting and vigilance reporting, solely harmonize activities on the MS level instead of utilising EU tools, which could serve as a one-stop shop for the entire EU. In this sense, further convergence would be beneficial for all stakeholders because it would further decrease regulatory complexity:

– Economic operators – no multiplication of activities in every MS.
– Administrators – decreased workload as many activities will take place at another MS or EU level.

62 Significant changes are determined based on MDCG 2020–3 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD, March 2020.

63 See: https://health.ec.europa.eu/system/files/2023-10/md_eudamed_roadmap_en.pdf.

64 Article 31 MDR requires economic operators to register to obtain a Single Registration Number or "SRN". Article 29 requires manufacturers to upload information about each device, including its UDI information.

– With decreased regulatory complexity, more devices can be expected on the single market, increasing competition. Lastly, this will increase medical device availability and patient safety, which are MDR goals.

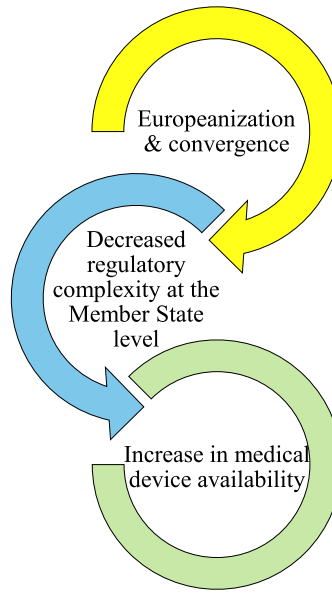

Fig. 3. Convergence – complexity – availability flow.

5. Conclusion

Regulation is the EU's legislative act used to reach unification. MDR, with its main objective to harmonize national laws, undoubtedly increased convergence, but it has not reached the level of unification nor supranational joint administrative capacities. However, some elements aim towards this direction. This matches the degree of convergence evaluated in this research. Therefore, MDR has reached its objective – harmonization. Moreover, MDR has the same level of convergence as MDD. In this third level, there is legal coordination among MSs per uniform administrative law principles and common rules.

Regulation as a means to (only) harmonize and not unify is noticeable in some other sectors, such as personal protective equipment and cosmetics. It is important to note that certain relevant elements of the MDR framework have already been unified, such as CE marking and EC conformity assessment procedures. We can also conclude that once relevant aspects of the MDR become effective, which rely upon EUDAMED, the MDR framework will reach the fourth and final convergence level, where EUDAMED will present supranational joint administrative capacity.

Finally, our findings demonstrate that the increased convergence in the medical device framework introduced by the MDR led to a conflicting outcome – instead of the expected decrease in regulatory complexity, it increased complexity. Table 1 shows that although the MDR has been applicable since 2021, several key elements are still ineffective due to EUDAMED delay. This increases regulatory complexity as regulatory requirements must be fulfilled on several horizontal and vertical levels. This should not be the case in multilevel governance systems. It is of utmost importance that policymakers, legislators, administrators, and experts work hand in hand when developing reforms that should converge the EU framework and avoid delays as they contribute to conflicting and unwanted outcomes.

While this article demonstrates the Europeanization and convergence level of the EU medical device framework and places convergence in relationship with regulatory complexity, it has certain limitations. The basis of the article is in a multilevel governance perspective, where the article does not discuss different EU integration processes. This paper opens exciting avenues for future research, such as the relationship between decreased regulatory complexity at the MS level and increased medical device availability.

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Rethinking Conscientious Objection to Mandatory Vaccination

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Keywords:
justice, conscience, European Court of Human Rights, the Convention for the Protection of Human Rights and Fundamental Freedoms, conscientious objection

Abstract: Among the member states of the Council of Europe, there is a consensus on the importance of vaccination as a successful and effective preventive health intervention. Every state aims to achieve herd immunity, i.e., a high vaccination rate of the population that will prevent the circulation of contagious diseases in the population and thus protect those who cannot be vaccinated due to age or poor health. However, despite the general recognition of the importance of vaccination, there is no consensus on a "single model" of how best to achieve the goals of mass immunization. Countries have different public health policies, so while the vaccination policy of some members of the Council of Europe is limited to a recommendation, others have made vaccination compulsory. Today, there are many opponents of vaccination and those who are hesitant. This paper will focus on those who refuse to be vaccinated based on a moral understanding of how to act in certain circumstances. The paper will explore whether countries imposing mandatory vaccination, with financial or other sanctions imposed in the case of non-compliance, should recognize the right to conscientious objection. This includes the right of adults to refuse vaccination, and respecting the religious and philosophical beliefs of parents

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who refuse to vaccinate their children. The article consists of two main parts. The first part will explore the legal-theoretical and legal-philosophical dimensions of the relationship between justice and conscience, with special emphasis on the interpretation of this relationship provided by the American political philosopher John Rawls. The second part of the paper will examine the issue of compulsory vaccination and conscientious objection through the prism of the rights provided for in the Convention for the Protection of Human Rights and Fundamental Freedoms.

1. Introduction

Among the member states of the Council of Europe, there is a consensus on the importance of vaccination, as "one of the most successful and cost-effective health interventions."[1] Vaccination as a medical practice is evidence-based and represents "a safe, effective way to achieve individual immunity from serious diseases, and prevents very significant morbidity and mortality."[2] Therefore, it seems understandable that "each State should aim to achieve the highest possible level of vaccination among its population."[3] The policy of mass vaccination should achieve herd immunity, i.e. a high vaccination rate in the population that will prevent the circulation of diseases in the population and thereby protect those who cannot be vaccinated due to age or poor health.[4] It can be said that vaccination also represents a positive obligation of the state "to take appropriate measures to protect the life and health" of its population (Articles 2 and 8 of the European Convention on Human Rights, hereinafter ECHR or Convention; similar obligations exist in other international human rights instruments).[5] However, despite the general recognition of the importance of vaccination, there is

1 ECtHR Judgment of 8 April 2021, Case Vavřička and Others v. The Czech Republic, application no. 47621/13, hudoc.int. § 277.

2 Steve Clarke, Alberto Giubilini, and Mary Jean Walker, "Conscientious Objection to Vaccination," *Bioethics* 31, no. 3 (Mar 2017): 156.

3 Vavřička and Others v. The Czech Republic, § 277.

4 Clarke, Giubilini, and Walker, "Conscientious Objection to Vaccination," 156.

5 Vavřička and Others v. The Czech Republic § 282.

no consensus on a "single model" of how best to achieve the goals of mass immunization.[6]

Each individual member state has discretion in choosing which healthcare policy model to adopt.[7] The European Court of Human Rights (hereinafter ECtHR or the Court) believes that domestic authorities are best positioned to balance "competing private and public interests or Convention rights."[8] At the same time, as the ECtHR points out, they have a wide margin of appreciation.[9] Countries have varying public health policies, so while the vaccination policy of some members of the Council of Europe is limited to a recommendation, others have made vaccination compulsory.[10] In the latter case, failure to vaccinate is usually followed by financial sanctions representing "direct penalties for failure to vaccinate."[11]

There are, however, other possibilities. States can set vaccination as a legal or factual prerequisite for employment or for undertaking certain activities.[12] The latter "conditional approach" was prevalent in many countries during the COVID-19 pandemic, when countries limited freedom of movement, international travel, and even domestic travel by making them conditional on having "vaccine passes." These documents were also required for entering public buildings, such as courts, potentially affecting the right to a fair trial (Article 6 of the ECHR). Additionally, vaccine passes were necessary for visits to places such as restaurants, cafes, museums, cinemas, and theatres.[13]

Although there is no single model for achieving a high vaccination rate, it is important to point out that no European country currently has

6 Ibid., § 278.
7 Ibid., § 285.
8 Ibid., § 275.
9 Ibid., § 285.
10 Ibid., § 278; Ian Leigh, "Vaccination, Conscientious Objection and Human Rights," *Legal Studies* 43, no. 2 (2023): 203.
11 Ibid.
12 Ibid.
13 Ibid.

a forcible vaccination regime.[14] Forcible vaccination is a model according to which vaccines are "administered against the will of the applicants."[15]

This is partly because, despite the consensus that exists in medicine, not everyone is convinced of the benefits of vaccination. There are many opponents of vaccination today, as well as those who are hesitant ("hesitant vaccine refusers").[16] The category of those who avoid vaccination is very diverse. Some do not vaccinate themselves or do not vaccinate their children because of doubts about medical science and its claims about the nature of the disease. In other words, they have doubts about the effectiveness and safety of vaccines. Another group are free riders who want to spare themselves even the "minimum risk" of rare health complications entailed in vaccination, but want to benefit from the herd immunity provided by others who have been vaccinated. They act out of self-interested motives, disregarding the value of social solidarity.[17] Whatever the reason, refusing to vaccinate undermines the possibility of achieving herd immunity.

Although there are various reasons for refusing vaccination, this paper will focus on those based on conscience.[18] More precisely, on a moral understanding of how to act in certain circumstances.[19] It will explore whether countries imposing mandatory vaccination, with financial or other sanctions imposed in the case of non-compliance, should recognize the right to conscientious objection. This includes the right of adults to refuse vaccination, and respecting the religious and philosophical beliefs of parents who refuse to vaccinate their children.

The article consists of two main parts. The first part will explore the legal-theoretical and legal-philosophical dimensions of the relationship between justice and conscience, with special emphasis on the interpretation of this relationship provided by the American political philosopher John Rawls. The second part of the article will examine the issue of compulsory

14 Vavřička and Others v. The Czech Republic § 278; Leigh, "Vaccination, Conscientious Objection and Human Rights," 203.

15 Vavřička and Others v. The Czech Republic § 276.

16 Leigh, "Vaccination, Conscientious Objection and Human Rights," 205.

17 Ibid., 220; Clarke, Giubilini, and Walker, "Conscientious Objection to Vaccination," 155; Vavřička and Others v. The Czech Republic § 279.

18 Clarke, Giubilini, and Walker, "Conscientious Objection to Vaccination," 155.

19 Leigh, "Vaccination, Conscientious Objection and Human Rights," 205.

vaccination and conscientious objection through the prism of the rights provided for in the Convention for the Protection of Human Rights and Fundamental Freedoms.

2. Justice and Conscience

Decisions regarding the pandemic should in some way be connected to ethical discourse. Some previous experiences from similar pandemics (such as the one in 2009 and bird flu H1N1) have shown the importance of the distributive justice principle, particularly in the context of vulnerable social groups. Social justice here comes into focus again as a crucial virtue of institutions within the framework of liberal constitutional democracies whose responsibility is to help the underprivileged.

One can think about justice from a legal perspective, which happens to be the most common approach to the subject. Legal professionals (expectedly) consider it to be a "decision-making principle aimed at tempering the rigidity of the civil law norm."[20] The logic of things leads one to conclude that form (the law) is above content (justice). Similar objections will be made to democracy as a political arrangement based on form without content. In such a political system, content comes second and form comes first. Suffice it to quote German liberal socialist Franz Oppenheimer and his famous statement that laws were "forced by a victorious group of men on a defeated group" in order to protect themselves.[21]

Returning to contemporary thought, one could ask another important question: Where does an individual's sense of justice come from? There is substantial cross-cultural research[22] suggesting that one's inner sense of justice, although quantitatively modified by cultural norms, is part of one's evolutionary heritage. Authors claim that behavioral biology, particularly the theory of evolution, leads to the conclusion that "moral traditions are cultural expressions of underlying cognitive and emotional

20 Vladimir Pezo, ed., *Pravni leksikon* (Zagreb: Leksikografski zavod Miroslav Krleža, 2007), 1189. This is also discussed in: Josip Berdica, *Pravednost i mišljenje kao prve vrline* (Zagreb: Jesenski i Turk, 2024), 214.

21 Franz Oppenheimer, *The State: Its History and Development viewed Sociologically* (New York: Vanguard Press, 1926), 15.

22 Owen D. Jones and Timothy H. Goldsmith, "Law and Behavioral Biology," *Columbia Law Review* 105, no. 2 (March 2005): 441.

pre-dispositions that are the products of evolutionary processes."[23] This ultimately means that "the power of culture to shape human behavior, while impressive, is limited – and in fact . . . there is good evidence to support the claim that the human ability to create culture is itself a result of evolved mental tools."[24]

These tools were created and developed because they helped man "survive and reproduce" successfully.[25] To quote historian Harari,[26] "humans have created imagined orders and devised scripts," which helped them organize into mass-cooperation networks. Perhaps it is in this sense that one could interpret Berdiaev's thought that all cultural accomplishments – including imaginary (legal) orders – "are symbolic rather than realistic."[27]

At this point, another issue to be considered is the question of law as a tool to achieve justice in organized societies. Society uses law as a tool to encourage its members to behave differently than they would in its absence while justice defines the fundamental purpose that law should serve. Expectedly, this "fundamental purpose" (often cited as "fundamental principle") "makes law highly dependent on sound understandings of the multiple causes of human behavior. The better those understandings, the better law can achieve social goals with legal tools."[28] Nevertheless, one should always take into account the warning given by Seneca the Elder: "Some laws, though unwritten, are more firmly established than all written laws."

One of the most important political philosophers, John. B. Rawls (1921–2002), brought social justice, justice in political institutions of "reasonably just societies," and problems of function and purpose of these institutions into the forefront of political, but also legal theory. Justice is "the first virtue of social institutions, as truth is of systems of thought," states Rawls at the beginning of his *A Theory of Justice* (1971), adding that unjust laws and institutions ought to be reformed or abolished. For Rawls, the

23 John Teehan, *In the Name of God: The Evolutionary Origins of Religious Ethics and Violence* (Chichester: Wiley-Blackwell), 4.

24 Ibid.

25 Ibid.

26 Yuval N. Harari, *Sapiens: A Brief History of Humankind* (London: Vintage Books, 2014), 149.

27 Nicolas Berdyaev, *The Meaning of the Creative Act* (New York: Collier Books, 1962), 298. For additional in-depth information on this topic, see: Berdica, *Pravednost i mišljenje kao prve vrline*, 216–20.

28 Jones and Goldsmith, "Law and Behavioral Biology," 405.

belief that justice is as important for living together as humans as truth is for understanding the world, is part of everyday intuition, deeply embedded within reason.[29]

However, as Italian liberal-socialist philosopher of law Norberto Bobbio rightfully points out, "the alpha and omega of political theory is the problem of government."[30] This is because, as he explains, political theory and philosophy revolve around questions of gaining, holding, losing, exercising, and defending power. This concerns the relationship between those in power and their subjects (in democracies these are political citizens assembled under liberal constitutional democracies). The entire history of political thought can be summarized as an emphasis on "duty of obedience" versus "right to resistance."[31] This leaves one with an open question: is there room for resistance to a government that imposes, for example, an obligation to be vaccinated during a pandemic? Can such resistance be legitimized? And, finally, can such resistance remain in the private sphere or should it also be taken to a public forum? Such questions only serve to guide this discussion: by addressing the topic of resistance, the right to resistance based on conscientious objection will be discussed.

As far as John Rawls is concerned, his philosophy explores ways in which people of different beliefs and goals may live together safely, fairly and well. In a society such as ours, a significant role is played by various institutions which are part of everyday dealings and interactions of its members. Speaking of duties and obligations of political citizens in liberal constitutional democracies, Rawls points out that a conscientious refusal is an act of "noncompliance with a more or less direct legal injunction or administrative order."[32]

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29 John Rawls, *A Theory of Justice: Revised Edition* (Cambridge: The Belknap Press of Harvard University Press, 1999), 3–4. For more about this important issue see: Berdica, *Pravednost i mišljenje kao prve vrline*, 83–106.

30 Norberto Bobio, *Doba prava: Dvanaest eseja o ljudskim pravima* (Beograd: Službeni glasnik, 2008), 113. This topic in the context of civil disobedience is particularly emphasized in: Berdica, *Pravednost i mišljenje kao prve vrline*, 165–99.

31 Bobio, *Doba prava: Dvanaest eseja o ljudskim pravima*, 113.

32 Rawls, *A Theory of Justice: Revised Edition*, 323.

Because the order is directed at the citizen, the government is (institutions are, to be exact) aware they are disobeying it.[33] If this were not the case, i.e. if citizens tried to hide their disobedience, this would better be termed "*avoidance* based on conscientious objection" than disobedience. In the case of the former, this can be described as passive inaction, while in the second case, the political person is a subject actively refusing to perform some legally binding act based on their own understanding of the principle of fairness. This is an important distinction when taking into account the level of moral responsibility for passive inaction as opposed to active refusal.

Conscientious refusal entails some key elements:

(1) It is not addressing the "sense of justice of the majority of the community," i.e. it is not "defined as a public act," which is why
(2) "Motivating principles of conscientious refusal need not be political" (they might, for example, be religious);
(3) "Motivating principles may not be shared with other members of the community – though they might be";
(4) "A principled omission need not be part of an effort to achieve reform" (of a law or other legal act).[34]

In summary, conscientious refusal is an individual's non-compliance with a legitimate legal order based on political, religious or other principles, which need not be shared by other members of the political community, without an end goal to achieve reform or abolish the legal act which the disputed order stems from, and without a desire to influence other members of the community by this act.[35]

There are four key requirements such a conception of conscientious objection should meet, with some variation, to be justified:

(a) efforts should be made to achieve satisfaction through standard means;
(b) the object of refusal must be an actual violation of the principle of justice;

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33 This is discussed in more detail in a slightly different context in: Berdica, *Pravednost i mišljenje kao prve vrline*, 157–63.

34 David Lyons, "Conscientious Refusal," in *The Cambridge Rawls Lexicon*, eds. Jon Mandle and David A. Reidy (Cambridge: Cambridge University Press, 2015), 139.

35 See: Berdica, *Pravednost i mišljenje kao prve vrline*, 158.

(c) the refuser must voluntarily express their stance that anyone else, should they be subjected to injustice in a similar way, has the right to protest in a similar way; and
(d) the act of disobedience must be rationally and thoughtfully planned in order to achieve the refuser's goals.[36]

When discussing Rawls, one needs to keep in mind his understanding of the political concept of a person and their relationship to freedom, because it forms the actual background of this conception of conscientious refusal. Only a political citizen rooted in their own understanding of good in a well-organized society of a constitutional democracy may use this instrument to uphold their personal understanding of good, i.e. justice. This instrument is, in essence, a realization of the principle of freedom of political citizens. Along with civil disobedience, it is one of the fundamental correctives of democratic institutions, notably laws, and, ultimately, law itself. Accordingly, Rawls says that citizens are understood as those who consider themselves free in three respects:

(1) "Citizens are free in that they conceive of themselves and of one another as having the moral power to have a conception of the good";
(2) Citizens "regard themselves as being entitled to make claims on their institutions so as to advance their conceptions of the good (provided these conceptions fall within the range permitted by the public conception of justice)";
(3) Citizens consider themselves "capable of taking responsibility for their ends and this affects how their various claims are assessed."[37]

It should be pointed out that a fundamental principle of liberal constitutional democracies and well-organized societies is the concept of freedom of conscience, i.e. the right to shape and develop thoughts in a way one feels most familiar, to choose a course of action and act in accordance to this conviction.[38] A political person understands themselves as not only inevitably bound to follow a certain concept of good, which they affirm at every moment, but also as capable of revising and altering this concept on

36 Dragan Vukadin, "Pravo prigovora savjesti," *Filozofska istraživanja* 23, no. 2 (2003): 426.
37 John Rawls, *Political Liberalism* (New York: Columbia University Press, 1996), 29–34.
38 See: Arsen Bačić, *Leksikon Ustava Republike Hrvatske* (Split: Pravni fakultet u Splitu, 2000), 339. Berdica, *Pravednost i mišljenje kao prve vrline*, 160.

reasonable and rational grounds, if they wish to do so. In other words, one has a "moral power to form, to revise and rationally to pursue a certain conception of the good."[39] This is especially evident when it comes to the moral identity of a political person. Citizens can have not only political, but also apolitical goals and loyalties. The latter serve to promote other values in their non-political lives and to promote the goals of organizations they belong to. "These two aspects of moral identity" (political and apolitical), says Rawls, "citizens must adjust and reconcile."[40] He continues that citizens are often unable to see themselves separately from certain religious, philosophical, and moral convictions, or certain long-standing preferences or loyalty to some concept of good. Still, in a well-organized society, citizens' political values and (apolitical) loyalties, as part of their non-institutional or moral identity, are approximately the same.

And what if they are not? What if one has no choice but to publicly advocate for one thing, while keeping in one's back pocket "quite a few other, potentially opposing values that may, or may not, prevail in case of conflict"?[41] When speaking of conscientious refusal, one needs to address the question of what should prevail in cases when personal conscience conflicts with legitimately imposed obligation. This was, of course, a particularly important issue in the recent crisis caused by the COVID-19 pandemic. The obligation to vaccinate was imposed on the members of society, which, according to some, violated the fundamental right to freely decide what is good for themselves and what is not. However, it is justified to ask the question: when should an individual's freedom give way to the freedom of others (to protect themselves from illness)? Which takes precedence – that individual's own concept of good or the principle of justice (inherent in a legitimately imposed obligation)? Rawls claims that life in a just society nourishes a sense of justice and hopes that today's liberal democracies will use their basic institutions in ways that promote a desire to cooperate (to bring together a personal concept of good and the principle of justice), and

39 Rawls, *Political Liberalism*, 72.

40 Ibid., 31.

41 Zoran Kurelić, "Pretpostavlja li Rawlsova koncepcija preklapajućega konsenzusa individualnu shizofreniju?," *Politička misao* 40, no. 1 (2003): 44.

strengthen a feeling of reciprocity and awareness of belonging to a wider community.[42]

It is fairly evident that (political or public) law(s) cannot always align with the dictates of conscience. However, the legal order aims to "realize the principle of equal liberty" for all potentially "opposing moral conceptions," which have an "equal place within a just system of liberty."[43] "In a free society," says Rawls, "no one may be compelled" to do something that would violate equal liberty or comply with "inherently evil commands."[44] Nevertheless, religious or moral principles that the conscientious objector invokes cannot be fully realized if their full realization would ultimately disrupt the principle of equal freedom of others. Rawls aptly concludes that it is a "difficult matter to find the right course when some men appeal to religious principles in refusing to do actions which, it seems, are required by principles of political justice."[45]

"In the little world in which children have their existence," says Pip in Charles Dickens's *Great Expectations*, "there is nothing so finely perceived and so finely felt, as injustice." What spurs action is not the realization that the world falls short of being completely just but that there are clearly remediable injustices around which one wants to eliminate.[46] Summarizing the role of conscientious refusal in modern democratic society, Rawls points out that such instances may, in a way, suggest that principles of justice are altogether guaranteed. What is more, conscientious refusal, when based on principles of justice among people, can also prevent the government from making unjust decisions. Thus, this refusal has a two-fold effect: explaining citizens' views ("the search for truth in the market of ideas") and controlling an unjust government ("the perception of participation was created in order to legitimise democratic political government").[47]

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42 Kurelić, "Pretpostavlja li Rawlsova koncepcija preklapajućega konsenzusa individualnu shizofreniju?," 45; see also: Berdica, *Pravednost i mišljenje kao prve vrline*, 161.

43 Rawls, *A Theory of Justice*, 325.

44 Ibid., 326.

45 Ibid., 325.; see also: Berdica, *Pravednost i mišljenje kao prve vrline*, 161–2.

46 Amartya Sen, *The Idea of Justice* (Cambridge: Belknap Press, 2009), vii; see also: Berdica, *Pravednost i mišljenje kao prve vrline*, 213.

47 Bačić, *Leksikon Ustava Republike Hrvatske*, 329–30.

3. Compulsory Vaccination and Convention Rights

The introduction of compulsory vaccination as "an involuntary medical intervention"[48] and as a way of restricting the right to respect for private and family life is, under the original meaning of Article 8 of the ECHR in the sense of originalist jurisprudence, present in American legal science.[49] The protection of private and family life, which is explicitly stated in the ECHR, could be restricted "for the protection of health or morals, or the protection of the rights and freedoms of others" (Article 8, Paragraph 2). In drafting this provision, the creators of the ECHR were inspired by Article 29 of the Universal Declaration of Human Rights.[50] However, any interference by public authorities with the exercise of this right must be "in accordance with the law" and "necessary in a democratic society" (Article 8, Paragraph 2). It is worth noting that although the ECtHR itself is not bound by the original meanings of the Convention, it has adopted "evolutionary interpretation" as its primary method of interpretation.[51] In other words, the Court views the ECHR as a "living instrument."[52]

The key difference between Articles 8 and 9 of the ECHR (Freedom of thought, conscience, and religion)[53] regarding the obligation to vaccinate is that Article 8 protects the autonomy of the individual, who is entitled to accept or refuse a medical intervention without the obligation to justify their decision.[54]

This understanding of autonomy does not distinguish between ethical and pragmatic reasons for refusing vaccination.[55] For example, following

48 Vavřička and Others v. The Czech Republic § 263.

49 Silvio Roberto Vinceti, "COVID-19 Compulsory Vaccination and the European Court of Human Rights," *Acta Biomedica: Atenei Parmensis* 92, no. 6 (2021): e2021472. https://doi.org/10.23750/abm.v92iS6.12333: 1–2.

50 "1. Everyone has duties to the community in which alone the free and full development of his personality is possible. 2. In the exercise of his rights and freedoms, everyone shall be subject only to such limitations as are determined by law solely for the purpose of securing due recognition and respect for the rights and freedoms of others and of meeting the just requirements of morality, public order and the general welfare in a democratic society." Ibid., 2.

51 Ibid., 3.

52 Ibid., 1.

53 Leigh, "Vaccination, Conscientious Objection and Human Rights," 209.

54 Ibid., 207.

55 Ibid.

the principles of alternative medicine is considered an exercise of autonomy.[56] Some individuals oppose vaccination because they do not trust modern medical science, believe that vaccination causes health problems, that vaccines are not effective in protecting against infectious diseases, that they are not produced following relevant standards, etc.[57]

ECtHR in the case of Solomakhin v. Ukraine,[58] which concerns the vaccination of an adult, determined that compulsory vaccination as an interference with the right to the protection of private life according to Article 8 ECHR, must be "in accordance with the law," pursue "one or more of the legitimate aims" (protection of health and rights of others recognized by Paragraph 2 of Article 8) and be "necessary in a democratic society."[59] The ECtHR Judgment of 8 April 2021, Case Vavřička and Others v. The Czech Republic (hereinafter Vavřička and Others v. The Czech Republic), which concerned the vaccination of children, also determined that there was no violation of Article 8 of the Convention.

Vaccine refusal on ethical grounds is of a different nature than that which is based on an individual's autonomy. It assumes freedom of conscience and moral integrity, and, as such, deserves stronger recognition than the exercise of autonomy when balanced against the protection of public health.[60] An opponent of vaccination appealing to conscience may consider it a matter of duty, where he or she is "compelled to act (or abstain) by his or her convictions," which have a binding nature for him or her[61] "even if it is to his or her own detriment."[62] Thus, individuals find themselves in a gap between legal and moral duties.

3.1. Conscientious Objection to Vaccination

While liberal democracies typically do not allow individuals exemption from legal obligations,[63] the constitutions of many countries permit conscientious

56 Ibid., 209.
57 Clarke, Giubilini, and Walker, "Conscientious Objection to Vaccination," 155.
58 The ECtHR Judgment of 15 March 2012, Case Solomakhin v. Ukraine, application No. 24429/03, hudoc.int.
59 Vavřička and Others v. The Czech Republic § 265.
60 Leigh, "Vaccination, Conscientious Objection and Human Rights," 209.
61 Ibid., 208.
62 Ibid.
63 Ibid., 217.

objection. This includes cases of exemption from the obligation of military service[64] due to the existence of "deep moral disagreements" or for "pragmatic" reasons, and cases of medical professionals exercising the right to conscientious objection regarding their professional obligation to perform abortions.[65] The problem with these exemptions arises when their number becomes significant, for example, if all doctors in a city or region refuse to perform abortions due to conscientious objection.

While conscientious objection is most often mentioned today in the context of the obligation of military service and the right of medical professionals not to perform abortions, it is interesting to note that this modern mechanism for protecting the moral convictions of individuals, found in numerous constitutions worldwide, actually first appeared in the context of vaccination.[66] Historically, the exercise of conscientious objection to compulsory vaccination of children first appeared in Great Britain, in the Vaccination Act of 1898. This was a response to the strong resistance to vaccination already present at the time. Resistance to vaccination decreased after the introduction of conscientious objection, and the vaccination rate of children increased. Based on this experience, Great Britain abandoned compulsory vaccination in 1946.[67] Respecting individuals' beliefs, as seen in this example, affects their perception of medical risks and alleviates their fears of harmful consequences.[68]

Conscientious objection can be based on religious or secular reasons, more precisely moral or philosophical ones.[69] In terms of religious beliefs, most religions follow the lines of medical science when it comes to

64 Clarke, Giubilini, and Walker, "Conscientious Objection to Vaccination," 155.

65 Leigh, "Vaccination, Conscientious Objection and Human Rights," 217; Clarke, Giubilini, and Walker, "Conscientious Objection to Vaccination," 156–7.

66 Daniel A. Salmon et al., "Compulsory Vaccination and Conscientious or Philosophical Exemptions: Past, Present and Future," *Lancet* 367 (2006): 440; Judith Rowbotham, "Legislating for Your Own Good: Criminalising Moral Choice, The Modern Echoes of the Victorian Vaccination Acts," *The Liverpool Law Review* 30 (2009): 32; Ivana Tucak, "Obvezno cijepljenje djece: za i protiv," in *Suvremeno obiteljsko pravo i postupak*, ed. Branka Rešetar et al. (Osijek: Pravni fakultet Osijek, 2017), 140.

67 Salmon, Teret, MacIntyre, Salisbury, Burgess, and Halsey, "Compulsory Vaccination," 438; Tucak, "Obvezno cijepljenje djece," 140.

68 Rowbotham, "Legislating for Your Own Good"; Salmon, Teret, MacIntyre, Salisbury, Burgess, and Halsey, "Compulsory Vaccination," 436; Tucak "Obvezno cijepljenje djece," 159.

69 Clarke, Giubilini, and Walker, "Conscientious Objection to Vaccination," 155.

vaccination. However, with regard to specific vaccines, there is resistance among members of some religions, and in this context, the question of recognizing conscientious objection may arise.[70] For Catholics, this is the case with "material indirectly derived from aborted human fetuses in the development of certain vaccines," while Hindus, Jews and Muslims object to vaccines that contain animal products, the consumption of which is forbidden by their religious laws.[71]

The issue of conscientious objection to compulsory vaccination touches on state neutrality, the right to religious freedom, and discrimination against individuals based on their beliefs.[72] The neutrality of the law depends on its justification or its outcomes.[73] If one were to justify laws that introduce mandatory vaccination, their goal seems neutral – to protect public health based on medical sources and data.[74] Such laws do not favor a specific conception of good nor do they assume the superiority of certain values over others.[75] As for the outcomes of such laws, one must distinguish between direct and indirect religious discrimination.[76] Direct religious discrimination occurs in cases where a person is treated less favorably than another based on their religion or belief, while indirect religious discrimination exists where people of a certain religion or belief find themselves at a disadvantage compared to others.[77]

Today, a compulsory vaccination regime is not an obstacle for some countries to allow conscientious objection.[78] The option to invoke conscientious objection based on parents' religious or philosophical beliefs

70 Leigh, "Vaccination, Conscientious Objection and Human Rights," 206–7.
71 Ibid.
72 Ilias Trispiotis, "Mandatory Vaccinations, Religious Freedom, and Discrimination," *Oxford Journal of Law and Religion* 11 (2022): 146.
73 Ibid., 148.
74 Ibid.
75 Ibid.
76 Ibid., 152.
77 Ibid.
78 Clarke, Giubilini, and Walker, "Conscientious Objection to Vaccination," 155–6.

when vaccinating children exists today, for example, in most federal units of the United States of America,[79] Australia, and the Czech Republic.[80]

Nevertheless, in other countries that have a compulsory vaccination regime, this institution is considered unacceptable. A case from Croatia will be presented here as an example. The Croatian Constitutional Court, in its decision on the constitutionality of legal regulations prescribing the obligation to vaccinate, took a rather stringent stance on the possibility of introducing conscientious objection. Vaccination is defined as a professional medical issue where conscientious objection is not allowed:

> Finally, the Constitutional Court considers it necessary to emphasise that in this particular case, it is a professional (medical) question, and not a question of realising the guarantee of freedom of conscience, belief, opinion, and religion in the sense of Article 40 of the Constitution and Article 9 of the Convention [ECHR – author's note].[81]

Interestingly, in the case of Vavřička and Others v. The Czech Republic, which was brought before the ECtHR and which will be discussed at the end of this article, France, as the third-party intervener, pointed out to the ECtHR that the introduction of a legal obligation to vaccinate is a neutral provision that applies equally to everyone regardless of "their thought,

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79 Currently, in the United States, 45 states and Washington, D.C. allow religious exemptions from vaccination, and 15 states allow philosophical exemptions. "States With Religious and Philosophical Exemptions From School Immunization Requirements," National Conference of State Legislatures, accessed February 1, 2024, https://www.ncsl.org/health/states-with-religious-and-philosophical-exemptions-from-school-immunization-requirements#:~:text=Currently%2C%2015%20states%20allow%20philosophical,Advisory%20Committee%20on%20Immunization%20Practices.

80 According to Miluše Kindlová and Ondřej Preuss, "The conscientious objection judgment I. ÚS 1253/14 defined the applicable test as: '(1) constitutional relevance of justifications of conscientious objection, (2) urgency of justifications provided by the individual appealing to conscientious objection, (3) consistency and cogency of these justifications (4) societal impact of a secular (or religious) conscientious objection recognised in the individual case." Miluše Kindlová and Ondřej Preuss, "Conscientious Objection to Compulsory Vaccination? Lessons from the Case-Law of the European Court of Human Rights and a Test Employed by the Czech Constitutional Court," *ICL Journal* 16, no. 4 (2022): 460. See also: Leigh, "Vaccination, Conscientious Objection and Human Rights," 217; Clarke, Giubilini, and Walker, "Conscientious Objection to Vaccination," 155.

81 Constitutional Court of the Republic of Croatia, U-I-5418/2008 U-I-4386/2011 U-I-4631/2011, 30 January 2014 § 6.5.1; Tucak, "Obvezno cijepljenje djece,"158.

conscience or religion" and therefore cannot affect the rights protected by Article 9 of the ECHR.[82]

3.2. Practice of the European Court of Human Rights

The ECHR does not specifically mention the right to conscientious objection. Convention jurisprudence initially interpreted the protection of expression of religion and belief provided for in Article 9 very restrictively.[83] In the case of Boffa and 13 Others v. San Marino,[84] the Commission indicated that public health regulations on compulsory vaccination are neutral with regard to the religious affiliation or belief of an individual and thus do not represent interference with the freedom protected by Article 9 of the ECHR.[85] In its decision:

> (…) the Commission held that, in protecting the sphere of personal beliefs, Article 9 did not always guarantee the right to behave in the public sphere in a way which was dictated by such beliefs and noted that the term "practice" did not cover each and every act which was motivated or influenced by a belief.[86]

A major turning point in the recognition that Article 9 encompasses conscientious objection was the Bayatyan v. Armenia case. It was the first time that the Court determined that Article 9 ECHR applies to conscientious objectors.[87]

In this respect, the Court notes that Article 9 does not explicitly refer to a right to conscientious objection. However, it considers that opposition to military service, where it is motivated by a serious and insurmountable conflict between the obligation to serve in the army and a person's conscience or his deeply and genuinely held religious or other beliefs, constitutes a conviction or belief of sufficient cogency, seriousness, cohesion and importance to attract the guarantees of Article 9.[88]

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82 Vavřička and Others v. The Czech Republic § 325.

83 Leigh, "Vaccination, Conscientious Objection and Human Rights," 210.

84 ECommHR Decision of 15 January 1998, Case Boffa and 13 Others v. San Marino, dec., Nos. 26536/95 and others.

85 Trispiotis, "Mandatory Vaccinations," 159; Vavřička and Others v. The Czech Republic § 331.

86 Vavřička and Others v. The Czech Republic § 331.

87 Leigh, "Vaccination, Conscientious Objection and Human Rights," 210, 220.

88 ECtHR Judgment of 7 July 2011, Case Bayatyan v. Armenia, application No. 23459/03 §110, hudoc.int.

The ECtHR ruled that the assessment of whether the expressed objection falls under Article 9 depends on the particular circumstances of each case.[89] In this case, the ECtHR viewed the ECHR as a living instrument, and the recognition of the right to conscientious objection to military service was based on developing a common approach to this issue among the member states of the Council of Europe.[90] However, in this judgment, the ECtHR says nothing about the possibility of using the right to conscientious objection outside the context of military service.[91]

The ECtHR has yet to facilitate a debate on the merits of, i.e. a comprehensive argumentation on the possibility of expressing a conscientious objection to performing an abortion.[92] In 2020, it declared inadmissible the application of two Swedish midwives who were denied employment because they were unwilling to participate in abortions due to their religious beliefs: Grimmark v. Sweden and Steen v. Sweden.[93]

3.3. Vavřička and Others v. Czech Republic

Before Vavřička and Others v. The Czech Republic, the ECtHR never questioned the applicability of Article 9 of the ECHR to the possibility of conscientious objection to vaccination.[94] The six applicants, Czech nationals, submitted ECtHR complaints against the Czech Republic claiming that the consequences of their non-compliance with the legal obligation to vaccinate according to Article 46(1) and (4) of the Public Health Protection Act[95] led to, among other things, a violation of their right to respect for private life under Article 8 of the Convention. Three of them, Mr. Vavřička, Ms. Novotná and Mr. Hornych, also complained that the fine imposed for

89 Ibid., § 332.

90 Wojciech Brzozowski, "The Midwife's Tale: Conscientious Objection to Abortion after Grimmark and Steen," *Oxford Journal of Law and Religion* 10, no. 2 (2021): 306.

91 Ibid.

92 Ibid., 302.

93 ECtHR Judgment of 11 February 2020, Case Ellinor Grimmark v. Sweden, application No. 43726/17, hudoc.int; ECtHR Judgment of 11 February 2020, Linda Steen v. Sweden, application no. 62309/17, hudoc.int; Brzozowski, "The Midwife's Tale," 298–316.

94 Vavřička and Others v. The Czech Republic § 331.

95 Zákon o právěního veřeního zdraví (Law No. 258/2000 Coll.).

non-vaccination or non-admission of their children to kindergarten violated their right under Article 9 ECHR.[96]

The controversial provisions of the Public Health Protection Act oblige all permanent residents of the Czech Republic, including foreigners, to be vaccinated against the diseases listed in it. This involves diseases that are well-known to medical science,[97] and the detailed conditions related to vaccination are prescribed by secondary legislation.[98]

In the case of children under the age of 15, their legal representatives are responsible for compliance with these obligations.[99] The consequence of not vaccinating is the impossibility of enrolling children in preschool facilities.[100] However, it is important to emphasize that, in this regard, an exception to vaccination is provided for children who cannot be vaccinated due to medical reasons.[101] Persons who violate the obligation to vaccinate commit "a minor offence punishable by a fine of up to 10,000 Czech korunas (CZK) (currently equivalent to nearly 400 euro (EUR))."[102]

It is interesting that the applicant, Mr. Vavřička, refused to vaccinate his children against only a few of the prescribed diseases: poliomyelitis, hepatitis B and tetanus. He pointed out in his application that in these cases there is no danger to public health. The last case of poliomyelitis in the Czech Republic was in 1960, hepatitis B is not transmitted through normal contact between people but is characteristic only of "high-risk groups," and tetanus cannot be transmitted between people at all.[103] In the last-mentioned case, herd immunity is not even necessary.[104]

96 Vavřička and Others v. The Czech Republic § 313.

97 Ibid., § 158.

98 Decree on Vaccination against Infectious Diseases No. 439/2000 Coll. "defines the scope of compulsory vaccination as comprising vaccination against diphtheria, tetanus, whooping cough (pertussis), Haemophilus influenza type b infections, poliomyelitis, hepatitis B, measles, mumps, rubella and – for children with specified health conditions – pneumococcal infections (sections 4, 5 and 6)". Vavřička and Others v. The Czech Republic §158.

99 Ibid., § 11.

100 Ibid., § 15.

101 Ibid.

102 Ibid., § 17: "Under section 29(1)(f) and (2) of the Minor Offences Act (Zákon o přestupcích) (Law no. 200/1990 Coll.)."

103 Ibid., § 24, § 180.

104 Ibid., § 288.

Evidently, he did not question the importance of vaccination against diseases that can be transmitted through normal human contact.

According to the Czech Constitutional Court, the criterion of consistency of beliefs was not met in the case of Mr. Vavřička. Mr. Vavřička only pointed out his reasons for opposing the vaccination of his children at a late stage of the proceedings, which were primarily related to his concern for the children's health, while his philosophical or religious reasons were only secondary.[105]

The Czech Government considered the submitted complaints about the violation of the rights from Article 9 to be essentially a reiteration of the complaints that were raised regarding the violation of Article 8 of the ECHR.[106]

Personal views on compulsory vaccination based on wholly subjective assumptions about its necessity and suitability did not constitute a "belief" within the meaning of Article 9 of the Convention.[107]

At the same time, it is important to emphasize that in such cases the courts must not engage in examining the "theological or normative" foundations of individual beliefs.[108]

In its assessment, the ECtHR pointed out that the three applicants sought protection for "their critical stance towards vaccination" by referring to Article 9. However, their objections were not motivated by their religious freedom, but by their freedom of thought and conscience.[109] The ECtHR referred to its reasoning in the case of Bayatyan v. Armenia[110] but also to its reasoning in the case of Pretty v. the United Kingdom, in which it pointed out that despite the firmness of someone's beliefs, "not all opinions or convictions constitute beliefs in the sense protected by Article 9."[111] As far as Mr. Vavřička is concerned,

105 Ibid., § 29.
106 Ibid., § 314.
107 Ibid., § 315.
108 Trispiotis, "Mandatory Vaccinations," 159.
109 Vavřička and Others v. The Czech Republic § 330.
110 Ibid., § 332.
111 ECtHR Judgment of 29 April 2002, Case Pretty v. the United Kingdom, application No. 47621/13, hudoc.int; Vavřička and Others v. The Czech Republic § 333.

> (…) Having regard to the conclusions reached by the domestic Courts (Supreme Administrative Court, Constitutional Court – author's note) in this regard, and considering that this applicant has not further specified or substantiated his complaint under Article 9 in the present proceedings, the Court finds that his critical opinion on vaccination is not such as to constitute a conviction or belief of sufficient cogency, seriousness, cohesion and importance to attract the guarantees of Article 9.[112]

The lack of "the consistency and credibility of the person's claims" applies even more to Ms. Novotná and Mr. Hornych, who did not even use these arguments before the domestic courts.[113]

The Court therefore agreed with the Czech government that the complaints filed claiming a violation of the rights from Article 9 are "incompatible ratione materiae" with that provision.[114]

4. Concluding Remarks

Unquestionably, individuals are being "morally harmed" when forced to act contrary to the beliefs that constitute their identity.[115] However, the issue of whether there should be a legal right to exemption from legal duty is still controversial.[116] It has been shown that Rawls insists that as political persons, people understand themselves as not only inevitably bound to follow a certain concept of good, which they affirm at every moment, but also capable of revising and altering this concept on reasonable and rational grounds. Even, they rather have a "moral power to form, to revise and rationally to pursue a certain conception of the good."[117] When talking about the obligation to vaccinate during the recent pandemic, one of the fundamental questions related precisely to an individual's freedom to decide, but also to society's obligation to take care of the general health of the population.

This is especially so in the case of compulsory vaccination, where the effects of this preventive medical measure cannot be realized unless a high degree of vaccination is achieved. The demands of those who oppose

112 Ibid., § 335.
113 Ibid., § 336.
114 Ibid., § 337.
115 Leigh, "Vaccination, Conscientious Objection and Human Rights," 218.
116 Kindlová and Preuss, "Conscientious Objection to Compulsory Vaccination," 450.
117 Rawls, *Political Liberalism*, 72.

vaccination based on their conscience can only be balanced with public health arguments if there are reasonably few of them in society.[118] In such cases, the "values of ethical independence, tolerance, and pluralism" may override the value of protecting public health.[119] Rawls is right when he claims that life in a just society nourishes a sense of justice and hopes that today's liberal democracies will use their basic institutions in ways that promote a desire to cooperate, and strengthen a feeling of reciprocity and awareness of belonging to a wider community. Life within the framework of political liberalism presupposes not only our sense of political justice but also our responsibility for it.

The ECtHR has yet to give its explicit answer to the question of whether conscientious objection to compulsory vaccination is entailed in Article 9 of the Convention.[120] This paper was in the first place an attempt to present an overview of the current practice of this Court concerning conscientious objection, as well as a critical analysis of that practice by legal scholars. The Bayatyan case, which dealt with the issue of exemption from military service, was a turning point in Convention jurisprudence on conscientious objection, being the first case in which it was explicitly said that Article 9 of the ECHR includes this right.[121] However, the Court, interestingly, never decided on the merits of the issue of whether health professionals have the right to conscientious objection to abortion.

Ilias Trispiotis rightly noted that in the Vavřička and Others v. The Czech Republic, the ECtHR did not rule out the possibility that Article 9 includes conscientious objection to compulsory vaccination.[122] It can only be concluded that the applicants have not convinced the Court that this instrument could be applied in their case.[123] When there are "serious and insurmountable" conflicts of an individual's conscience with their legal obligations, member states are obliged to explore them.[124]

118 Leigh, "Vaccination, Conscientious Objection and Human Rights," 220.
119 Trispiotis, "Mandatory Vaccinations," 160.
120 Kindlová and Preuss, "Conscientious Objection to Compulsory Vaccination," 447.
121 Brzozowski, "The Midwife's Tale," 305.
122 Trispiotis, "Mandatory Vaccinations," 159.
123 Ibid., 159.
124 Ibid.

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