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**DIFFERENT LEGAL ASPECTS OF MANDATORY  
VACCINATION POLICIES**

**KOHUSTUSLIKU VAKTSINEERIMISKAVAGA KAAS-  
NEVAD ÕIGUSLIKUD ASPEKTID**

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## **ABSTRACT**

Mandatory vaccination policies are claimed to be a threat on human rights legislation due to their invasive nature. Those who are anti-vaccine say that body integrity must be guaranteed and cannot be derogated by state via a mandatory vaccination policy. Health care staff fears for their fundamental rights in their places of work. There is great concern mandatory immunization affects the right to family life and privacy, as governed by Article 8 of the European Convention on Human Rights. States defend their mandatory policies by the protection of collective immunity and public safety. A question arises, whether mandatory vaccination policies can be enforced staying in line with human rights and family law legislation?

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## INTRODUCTION

As states are drafting more exhaustive vaccination policies than ever, the topic of mandatory vaccinations produces a tremendous amount of conversation around the world. The question of whether enforcing mandatory vaccination policies breaches the fundamental rights of people is debated, not only from ethical, but also from a legal point of view. People demand to know how something so invasive could be considered proportionate and can be enforced by legislation and what is the justification for this?<sup>1</sup> There has been a strong resistance against mandatory vaccinations in the past years and especially the word “mandatory” seems quite ominous in the minds of people.<sup>2</sup> Vaccinations have inevitably experienced a drastic transformation from experimental medical ventures to commonly accepted lifesavers.<sup>3</sup>

Public health and vaccinations are said to have an indisputable correlation. When it comes to preventing and controlling disease, vaccine programs and regulations have been put in place and are enforced.<sup>4</sup> Recognizing personal responsibility is unattainable regarding public health since people who are adequately immunized do not only protect themselves, but also those, who have not been or cannot be immunized due to various reasons.<sup>5</sup> Therefor there is a certain sense of a social contract of tending to one another. Mandatory vaccination policies are aimed at those who would not otherwise submit to proper immunization. Mandatory immunization is usually defended with a utilitarian point of view: if a person is adequately immunized, they protect themselves and others

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<sup>1</sup> Walene, J. (1995). *Immunization: The Reality Behind the Myth*. Second edition. London: Bergin and Carvey.

<sup>2</sup> Omer, S. et al. (2009). Vaccine Refusal, Mandatory Immunization, and the Risks of Vaccine-Preventable Diseases. *The New England Journal of Medicine*. Volume 360, 1981-1988.

<sup>3</sup> Allen, A. (2007). *Vaccine: The Controversial Story of Medicine's Greatest Lifesaver*. 1<sup>st</sup> ed. United States of America. p.27.

<sup>4</sup> Haverkate, M. et al. (2012). *Mandatory and Recommended Vaccination in EU, Iceland and Norway : Results of the VENICE 2010 survey on the ways of implemeting national vaccination programs*. Accessible : <http://www.euro-surveillance.org/content/10.2807/ese.17.22.20183-en> , 31 May 2018.

<sup>5</sup> Allen. (2007). *Supra nota 3*, p.17.

around them and also choose the inexpensive vaccination instead of a costly treatment for an illness that could have been prevented.<sup>6</sup> Different states have a different understanding on how to draft a policy that works the best for people in all different situations. Other states have decided to enforce mandatory vaccination policies, others use a mixed regime and some states have decided to leave it up for the individuals to decide whether they want the immunization or not.<sup>7</sup>

Forcing citizens in mass-immunization regimes has provoked controversial conversation regarding the body integrity of people, as well as fear of the threat mandatory vaccinations might bring on free consent and eventually, human rights.<sup>8</sup> International Human Rights Law legislation brings notion to the fact that a free and informed consent is especially important in the medical field, as well as the right to body integrity. This is mentioned in the Article 3 of the Charter of Fundamental Rights of the European Union. Job seekers might also find themselves in a discriminatory position, if their immunization is not up to standard or they refuse to get vaccinated and in a globalizing world this creates an issue of equality and human rights. Discrimination is prohibited under all circumstances in the Article 14 of the European Convention on Human Rights.

Families with distinctive decisions and ethics are challenged and children are put into an isolated position based on their parents' decision not to vaccinate, even though all family units and their privacy should be respected according to Article 8 the European Convention on Human Rights. In this case, states willingly accept the fact that serving the common good surpasses the rights of an individual. International conventions promote and protect family values, but the state can still interfere into very personal matters, such as health care, even though state interference is not always considered beneficial, as mentioned in Article 8. Parental responsibility extends to not only the decisions parents decide to make regarding their own children, but in the case of collective immunization these decisions extend to other children too.<sup>9</sup> The welfare of a child must always be protected, and this seems to be a common legal viewpoint from all possible angles. Immunization may be one of the preventing factors standing in the way of equality of children and their right to education, since some states do not accept children without immunization into state schools or

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<sup>6</sup> Diodati, C. (1999). *Immunization: History, Ethics, Law and Health*. Second edition. Canada: Intergral Aspects Incorporated. p.157.

<sup>7</sup> Haverkate, M. et al. (2012). *Supra nota 4*.

<sup>8</sup> Grisso, T., Appelbaum, P. (1998). *Assessing Competence to Consent to Treatment*. New York: Oxford University Press. p.6.

<sup>9</sup> Allen. (2007). *Supra nota 3*, p.17.

other institutions.<sup>10</sup> The decision of the parents not to immunize due to safety concerns has also caused the resurgence of some preventable diseases.<sup>11</sup>

Almost every vaccine in the market has experienced some sort of resistance and at least careful evaluation before being fully accepted to the recommended vaccination policies. There is always the issue of liability regarding vaccines. People must be able to trust the vaccines and the vaccine producers and responsibility must be taken if there is any sort of a product defect.<sup>12</sup> This is supported by both European and international legislation. In case of insurances many companies do not currently take immunization into consideration in their insurance policies, but it will be seen whether this will change in the near future or not.

The aim of the paper is to present the contrasting legal aspects that relate to mandatory immunization and introduce the different attitudes that different states and their citizens demonstrate towards these policies. This aim is to be achieved with the research question of: **Does enforcing mandatory immunization programs impose a risk on international human rights by derogating individuals' right to family life?** Secondly the thesis will look at the international covenant: **Do different states comply or conflict with the Article 12 of the International Covenant on Economic, Social and Cultural Rights when imposing mandatory vaccination policies?** Sceptics say that the harm done by vaccines is more than the benefit gained but evidentially the decrease in infectious diseases gives ground for those promoting mandatory vaccination policies around the world. The hypothesis of the thesis stems from this statement: **Mandatory vaccination policies can be legally enforced to maintain collective health and these policies can align with the demands of human rights law and family law.**

The structure of the thesis is divided in three main parts. The first part of the thesis is a short introduction overviewing the history of vaccinations and mandatory vaccination policies. Secondly the thesis goes through some important legislation regarding human rights law and family law and how they dictate issues regarding mandatory vaccination policies. Finally, there are conclusions that will be drawn from the legislation at hand.

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<sup>10</sup> Haverkate, M. et al. (2012). *Supra nota 4*.

<sup>11</sup> Maglione, M., Das, L., Raaen, L. et al. (2014). Safety of Vaccines Used for Routine Immunization of US Children: A Systematic Review. *AAP Journals*. Vol 134. Issue 2, 325-37.

<sup>12</sup> Institute of Medicine (US) Committee on Review of Priorities in the National Vaccine Plan. *Priorities for the National Vaccination Plan*. Washington (DC). National Academic Press. Washington (2010). p. 243-244.

In this thesis the used research methods are qualitative, and the data used will be both normative sources and also authoritative sources, such as case law.<sup>13</sup> The used methodology used is the traditional legal dogmatic research method of describing and analyzing the current relevant legislation of human rights law and family law.<sup>14</sup> The author has chosen this methodology since the research is focusing on how the current legislation regarding mandatory vaccinations could affect human rights and family law. Another method is the sociological approach to law which will be used in analyzing how the different societies concern the mandatory vaccination policies.<sup>15</sup> There is an increasing knowledge about the reality of law and this is shown when heated conversations on mandatory vaccinations rise and people do not want to follow the law unconditionally if it imposes a risk to them.<sup>16</sup> Therefore the sociological approach to law-analysis will also be essential.

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<sup>13</sup> Van Hoecke, M. (2011). *Methodologies of Legal Research*. United Kingdom: Hart Publishing Ltd. p. 11.

<sup>14</sup> *Ibid.*

<sup>15</sup> Šlapkauskas, V. The Significance of the Sociological Approach to Law for the Development of Jurisprudence. *Societal Studies Reseach Journal*. Vol 4 No 8. (2010).

<sup>16</sup> *Ibid.*

# 1. HISTORY OF VACCINATIONS

Edward Jenner has been said to be the father of modern vaccinations. Before Edward Jenner's innovation there were several methods that were the predecessors of vaccinating. Jenner, however, began "vaccinology" in 1796.<sup>17</sup> Discovering that taking pus out of a lesion in the hand of a milkmaid and injecting it into a young boy, the epidemic disease would not be as severe as it would have been, had it not been without the vaccine.<sup>18</sup> The predecessor of this was the so-called variolation where the virus would be produced from a sick patient's pustule directly to a healthy person's skin with a sharp object, such as a knife.<sup>19</sup>

In the first two decades the smallpox virus was lethal especially in the towns of the United States, especially Boston. In 1726 a statistic was published showing that only 3 percent of the patients had died under variolation whereas by comparison over 14 percent of the population in Boston who got ill of smallpox the natural way had died.<sup>20</sup> Already during the 1700s there were people who took a stand against the variolation procedure, though their point of view was the religious one saying that the variolation was "against the will of God".<sup>21</sup> When Edward Jenner introduced his vaccine, the variolation procedure had become fairly safe and mostly effective and the population in both England and the United States was growing at a fast rate.<sup>22</sup> Vaccines became more well-known and by the year 1801 about 100,000 people in Europe had received a vaccination and before the change of decade over a million were vaccinated.<sup>23</sup>

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17. Stern, AM., Marcela, H. (2005). The History of Vaccines and Immunization: Familiar Patterns, New Challenges. *Health Affairs*. Vol. 24 no. 3, 611-621.

<sup>18</sup> Allen. (2007). *Supra nota* 3, p.27.

<sup>19</sup> *Ibid.*

<sup>20</sup> *Ibid.*, p. 32-33.

<sup>21</sup> *Ibid.*

<sup>22</sup> *Ibid.*, p. 44-45

<sup>23</sup> *Ibid.*, p. 49-50

## 1.1 First mandatory vaccination policies

After the successful public introduction to vaccines, many governments sought to create mandatory vaccination laws. In 1871 the Parliament of England established the Vaccination Act which made it mandatory to go through the vaccination procedure.<sup>24</sup> Germany on the other hand made it compulsory in 1874 to have all German children vaccinated. The United States followed with Boston becoming the first city with a mandatory vaccination law in 1827.<sup>25</sup> Even though the compulsory vaccinations were considered having a favorable outcome, the controversy over mandatory vaccinations grew greater and led to the largest uprising against a medical practice of all time. In 1889 the Royal Commission on Vaccinations took upon determining whether a vaccine was safe or not.<sup>26</sup> A better knowledge of the immune system and how it responds to pathogens was achieved and this led to new vaccines, such as the ones against diphtheria and tetanus.<sup>27</sup>

## 1.2 The first public resistance

As governments tried making public health a matter they could control, the public answered by demanding better and safer living conditions and the concern over possible bacteria and unhygienic conditions involved in the vaccination procedure raised suspicions in the minds of people.<sup>28</sup> The resistance in Britain was strong and eventually vaccination rates fell from 80 percent in 1898 to 18 percent in 1948.<sup>29</sup> The common census behind the anti-vaccine movement was the idea that the gravity of disease had been exaggerated by the vaccine manufacturers and the naturalist movement was on the forefront of the fight.<sup>30</sup> Whereas Britain had surrendered to the resistance, the US was only starting the campaigning for mandatory vaccinations. In Canada, the use of more safe medicine, such as penicillin, was generally introduced to the public.<sup>31</sup> State laws were developed and children that had not been vaccinated were excluded from schools in many cities.<sup>32</sup> During the war times the British, Canadian and French armies adopted the tetanus vaccination whereas in the

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<sup>24</sup> *Ibid.*, p. 59-65

<sup>25</sup> *Ibid.*

<sup>26</sup> *Ibid.*

<sup>27</sup> Diodati. (1999). *Supra nota* 6, p.8.

<sup>28</sup> Allen. (2007). *Supra nota* 3, p. 59-65.

<sup>29</sup> *Ibid.*

<sup>30</sup> Steiner, R. (1922). Illness Occurring in Different Periods of Life. *Health and Illness*. Vol. 1, 34.

<sup>31</sup> Diodati. (1999). *Supra nota* 6.

<sup>32</sup> Allen. (2007). *Supra nota* 3, p.69.

German troops, around 80 cases of tetanus were reported by Allied spies.<sup>33</sup> It was later revealed that the Nazi troops were testing vaccines on concentration camp prisoners and especially a typhus vaccine was under development adding to the burden of the horrific war crimes of the Second World War.<sup>34</sup>

### 1.3 Later decades

The main struggle during the 1950s was the polio vaccine which was successfully brought available to the public in 1955.<sup>35</sup> During the research for the vaccine, over 200 clinical strains of poliovirus were isolated from patients and eventually a new testing method was brought in the attention of the researchers.<sup>36</sup> During the 1960s the most concerning disease was measles that at its most severe caused brain-damage and deafness.<sup>37</sup> After founding the World Health Organization and United Nations Children's fund, vaccines were campaigned more successfully and broadly to the public and immunization of children improved in the developing countries as well.<sup>38</sup> By the end of 1960s American children were generally vaccinated against 8 different diseases and vaccinating a child was considered a legal responsibility of the parents.<sup>39</sup> During the 1970s numerous vaccines were already available to the public and a rubella episode that reaped Europe and the US provided new knowledge on the connection of the rubella disease and possible congenital birth defects such as the CRS; a congenital rubella syndrome.<sup>40</sup> A vaccine was developed by cultivating the virus in aborted fetal tissues.<sup>41</sup> Every decade brought either singular or combination vaccines into public distribution and during the 1980s hepatitis A and B vaccines were also brought into the vaccine pool.<sup>42</sup>

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<sup>33</sup> *Ibid.*

<sup>34</sup> *Ibid.*

<sup>35</sup> Stern, Marcela. (2005). *Supra nota* 17.

<sup>36</sup> Chase, A. (1982). *Magic Shots: A Human and Scientific Account of the Long and Continuing Struggle to Eradicate Infectious Diseases by Vaccination*. NY: William, Morrow and CO., Inc., 48.

<sup>37</sup> Stern, Marcela. (2005). *Supra nota* 17.

<sup>38</sup> *Ibid.*

<sup>39</sup> Allen. (2007). *Supra nota* 3, p.59-65.

<sup>40</sup> Diodati. (1999). *Supra nota* 6. Page 11.

<sup>41</sup> *Ibid.*

<sup>42</sup> *Ibid.*

## 2. DIVERSE VACCINATION POLICIES

### 2.1 International perspective

The aims of current vaccination policies emphasize the relevance of mass-immunization as a protecting factor of the public.<sup>43</sup> The vaccination policies are usually updated if there are: changes to the incidence of contagious diseases, vaccine development, changes in risk groups, clear negative effects caused by vaccination, or changes in vaccine effectiveness.<sup>44</sup>

A differentiation between recommended and mandatory vaccinations and policies must be made. A recommended vaccination refers to a vaccination that is listed in the national vaccination program for certain groups or everyone.<sup>45</sup> A mandatory policy, however, refers to a vaccination which every child must receive without consideration to parents' wishes.<sup>46</sup> An economic consequence might follow if the immunization program is not followed.<sup>47</sup> Internationally, there is a wide range of different perspectives when it comes to mandatory vaccination policies. The World Health Organization (WHO) does not have an official unison view on mandatory vaccination policies but it does understand the view of those countries that want to enforce one.<sup>48</sup>

In the United States mandatory vaccinations are given to school children before entering school but some exceptions are allowed under medical, philosophical and religious grounds.<sup>49</sup> The granting of an exception is also handled in various ways in different states. In some states, a notarized certificate providing justification is needed whereas in some states an exemption can be granted

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<sup>43</sup> National Institute for Health and Welfare. (2018). *National vaccination programme*. Accessible: <https://thl.fi/en/web/vaccination/national-vaccination-programme> , 31 April 2018.

<sup>44</sup> *Ibid.*

<sup>45</sup> Haverkate, M. et al. (2012). *Supra nota 4.*

<sup>46</sup> *Ibid.*

<sup>47</sup> *Ibid.*

<sup>48</sup> Walkinshaw, E. (2011). Mandatory Vaccinations: The international landscape. *Canadian Medical Association*. Vol 183, Issue 16.

<sup>49</sup> *Ibid.*

upon parents' request.<sup>50</sup> The precedent case used as a basis for the mandatory vaccinations in the US is the 1905 *Jacobson V Massachusetts* case where the US Supreme Court held that states have the authority to enforce mandatory vaccination laws.<sup>51</sup>

In Australia, the state has taken a different kind of stance towards vaccinations. The state has not made it compulsory to vaccinate children, but parents are given a small financial compensation if the child meets all immunization requirements.<sup>52</sup> If an epidemic of disease preventable by vaccination breaks, the children that are not immunized are excluded from lectures at schools even though schools do not necessarily require all children to be vaccinated.<sup>53</sup> This is a policy that works through the means of positive affirmation rather than handing out sanctions.<sup>54</sup>

## 2.2 European vaccination policies

In European states the vaccination policies vary dramatically. The European Union does not enforce regulations on vaccinations so there is no uniform vaccination policy. The countries are enforcing different kinds of vaccination regimes. For example, in Latvia there is no mandatory vaccination policy enforced by law but those health care workers who provide vaccinations must be immunized themselves and in state institutions vaccinations are mandatory.<sup>55</sup> Vaccinations are also offered free of charge and those individuals who refuse to be vaccinated are allowed to do so, but the health care providers must then explain, what could be the consequences of refusing the vaccination.<sup>56</sup> The Finnish vaccination policy takes in to account nine infectious diseases including diphtheria, pertussis and polio and 95 percent of Finnish children are vaccinated against these

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<sup>50</sup> *Ibid.*

<sup>51</sup> Court decision, 20 February 1905, *H. Jacobson v Commonwealth of Massachusetts*. 197 US 11.

<sup>52</sup> Walkinshaw, E (2011). *Supra nota* 48.

<sup>53</sup> *Ibid.*

<sup>54</sup> Puppink, G. (2017). *Can one refuse compulsory vaccination? The European Court will soon decide*. Accessible: <https://eclj.org/conscientious-objection/echr/refus-de-la-vaccination-obligatoire--la-cour-europenne-tranchera-bientt>, 4 April 2018.

<sup>55</sup> Walkinshaw, E (2011). *Supra nota* 48.

<sup>56</sup> Healy, Pickering. (2010). How to communicate with Vaccine-Hesitant Parents. *AAP Journals*. Vol. 127, Issue Supplement 1.

diseases.<sup>57</sup> The Finnish compliancy to vaccination policies is very good in general and all the vaccines are free of charge and voluntary.<sup>58</sup>

Slovenia on the other hand holds one of the most comprehensive mandatory vaccination policies in the world and exceptions based on religious reasons are not allowed.<sup>59</sup> The vaccination policy comprehends nine mandatory vaccinations and all of the vaccinations are given to the child within 18 months of the birth and some are given again before the child starts school.<sup>60</sup> The question arises, whether not allowing exceptions on religious basis is against the article 18 of the Universal Declaration of Human Rights that grants the freedom of religion? Those who claim that the Declaration is breached against, say that if the vaccination process is against a part of the religious conviction of the person, they should be allowed to refuse immunization based on their human rights. On the other hand, the opposing view is that collective immunity must be protected and cannot be diminished due to a religious or conscious conviction.

The French government has already announced its will to include eleven mandatory vaccines in the national vaccination program for children under two years old and the Italian government announced its so-called Lorenzin decree in 2017, making ten vaccines compulsory and free of charge to children aged 0-16 years.<sup>61</sup> Schools in Italy will only accept a letter written by a doctor stating medical facts why a child cannot be vaccinated and a failure to vaccinate can lead to a fine between 100 and 500 euros.<sup>62</sup> There is, however, a precedent case that could undermine the intentions of the Italian Lorenzin decree. The *Pavel Vavřiča and others v Czech Republic* case brought forward a question on the fines laid upon families that refused to vaccinate their children. The European Centre for Law and Justice intervened in the case giving its opinion, which stated that rather than imposing sanctions, emphasis should be on pedagogy and recommendations.<sup>63</sup> Therefore the policies of those enforcing mandatory vaccinations would not comply with the precedent of the case. It is also vastly argued that the emotional perspective of parents cannot be valued over the collective benefit of immunization.

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<sup>57</sup> Rapola, S. (2007). National immunization program in Finland, *International Journal of Circumpolar Health*. 66:5, 382-389

<sup>58</sup> National Institute for Health and Welfare. (2018). *Supra nota* 43.

<sup>59</sup> Walkinshaw, E. (2011). *Supra nota* 48.

<sup>60</sup> *Ibid.*

<sup>61</sup> The Local. (2017). *Compulsory Italian School Vaccinations: How it works*. Accessible: <https://www.thelocal.it/20170830/compulsory-italian-school-vaccinations-how-it-works> , 1 April 2018.

<sup>62</sup> *Ibid.*

<sup>63</sup> Puppincck, G. (2017). *Supra nota* 54.

## 2.3 The VENICE effort

Even though the European Union does not enforce common vaccination policies and does not require Member States to establish mandatory laws regulating vaccinations, there have been efforts to establish some common ground through the Vaccine European New Integrated Collaboration Effort (VENICE).<sup>64</sup> The VENICE projects have had a relevant impact in sharing expertise, establishing computerized immunization registries, exchanging vaccine coverage data and designing immunization strategies.<sup>65</sup> If the European Union was to establish a common vaccination law or regime, projects like the VENICE effort would be a valuable base for data and registry.

According to surveys conducted by VENICE in 2010 with all 27 Member States, Iceland and Norway, they established that 15 of the states do not have mandatory vaccinations.<sup>66</sup> There are 14 countries that have, by legislation, at least one mandatory vaccine.<sup>67</sup> Some countries have a mixed strategy and where some vaccinations are mandatory, others are merely recommended.<sup>68</sup> It has been discussed that mandatory vaccination policies are not necessarily needed since the European compliance with the recommended vaccinations is, in general, very high.<sup>69</sup> There are not only differences between the types of vaccinations given, but also between the timing of the immunization and the doses that are given.<sup>70</sup> What can definitely be extracted from research results is that timing of vaccinations between low, median and high income families differ a lot and usually, the lower the income of the family is, the longer the delay extends.<sup>71</sup> In some countries there are consequences if there is a delay in immunization and citizens can have difficulties entering state institutions in order to protect the mass immunization.<sup>72</sup> Some states even wager penal consequences to enforce immunization.<sup>73</sup>

Overall, the way different countries enforce their vaccination policies vary and their policies seem to stem from historical and cultural reasons more than evidence-based medical observations or

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<sup>64</sup> Haverkate, D'Ancona, Giambi, et al. (2012). *Supra nota 4*.

<sup>65</sup> Vaccine European New Integrated Collaboration Effort. (2018). *The Project*. Accessible: [http://venice.cineca.org/the\\_project.html](http://venice.cineca.org/the_project.html) , 10 February 2018.

<sup>66</sup> *Ibid.*

<sup>67</sup> *Ibid.*

<sup>68</sup> *Ibid.*

<sup>69</sup> *Ibid.*

<sup>70</sup> *Ibid.*

<sup>71</sup> Clark, Anderson. (2009). Timing of children's vaccinations in 45 low-income countries and middle-income countries: an analysis of survey data. *The Lancet Journal*. Vol 373, Issue 9674. P. 1543-1549.

<sup>72</sup> Haverkate, D'Ancona, Giambi, et al. (2012). *Supra nota 4*.

<sup>73</sup> *Ibid.*

research.<sup>74</sup> The VENICE effort has a difficult premise for establishing a commonly accepted regime for mass immunization and thus far the effort and its participants have remained as mere observers. The effort does, however, intend to establish common guidance on European immunization systems.<sup>75</sup>

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<sup>74</sup> *Ibid.*

<sup>75</sup> Vaccine European New Integrated Collaboration Effort. (2018). *Supra nota* 65.

### **3. HUMAN RIGHTS LAW AND VACCINES**

#### **3.1 International Covenant on Economic, Social and Cultural Rights**

The mandatory immunization must be analyzed from different perspectives. The mandatory immunization and its issue regarding human rights presents itself in various forms. Mandatory vaccinations affect individuals, their education and religious views, individuals' free consent, health care personnel's obligations and rights, the status and opportunities of foreign citizens, body integrity and the issues of privacy.

The International Covenant on Economic, Social and Cultural Rights guarantees all people their dignity and body integrity, but the key element when evaluating human rights law and the issue of mandatory vaccination policies would, however, lie upon the premise of Article 12 of said Convention. The Article 12 is set out to guarantee that the parties of the Covenant take necessary steps to prevent, control and treat diseases whether epidemic, work-related, or endemic in order to make sure everyone gets to enjoy the utmost great physical and mental health. This Article can be directly interpreted to cover immunization as well.

The controversy lies within the fact that if a party to the convention, for example a state or government, are to follow Article 12 of the Covenant, the success of preventing and controlling of diseases ultimately demands the establishing of a vaccination policy. If a state does not make sure the majority of people are immunized, are they breaching the rules of the Covenant by not preventing and controlling diseases as they should? Those who are pro-vaccination could say that states are merely taking the necessary step mentioned in Article 12 in preventing diseases by enforcing mandatory vaccinations. The opposing perspective says that under human rights law, states do not have the power to decide on enforcing mandatory vaccinations, because this is a breach of the rights of an individual.

Article 15 of the Covenant on the other hand guarantees that everyone has the right to enjoy the benefits of scientific improvements and developments. The opinions on this matter are controversial as well and those who are pro-vaccine state that this article can be directly used in defending vaccines. After all, the role of immunization has been indisputable in preventing disease and can be seen as a benefit of scientific development.<sup>76</sup>

### 3.2 Health care workers' rights

Article 7 of the Covenant states that the parties must guarantee all workers safe and healthy living conditions. Based on this, different workplaces are therefore allowed and even more so, obliged to make sure all the workers are up to standard with the mandatory health procedures. The Covenant can therefore be interpreted in two ways: from state perspective it is said if states enforce mandatory immunization, they are creating a safe and a healthy working environment. The perspective of nurses, however, seems to be that states and the employer are breaching the Covenant by mandating vaccinations for the health care staff. Workers often plead the right to body integrity, which usually is determined by acquiring the right by default not to have a body or person intervened and a state cannot harm a person's health.<sup>77</sup>

The most discussed vaccine in the recent years has been the mandatory influenza vaccine all health care workers must obtain in order to be able to work in their health care position.<sup>78</sup> The Finnish legislation *Tartuntatautilaki* has determined it is mandatory for nurses and doctors in Finnish public and private hospitals and health institutions to have, not only the vaccines listed in the national vaccination policy, but also the influenza vaccine, which is to be given yearly.<sup>79</sup> This has caused an outrage among the Finnish healthcare workers saying that it is a breach in regard to their body integrity and a referendum is proposed for ending the policy of nurses' mandatory vaccinations on the basis that there is not enough evidence on the effectiveness and safety of the vaccine.<sup>80</sup> By stating their opinion openly they are also protected since everyone has the freedom of opinion and expression and the nurses also have the right to obtain correct and impartial information on the

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<sup>76</sup> Allen. (2007). *Supra nota 3*, p.17.

<sup>77</sup> Citizen Information Board. (2018). Fundamental Rights under Irish Constitution. [http://www.citizensinformation.ie/en/government\\_in\\_ireland/irish\\_constitution\\_1/constitution\\_fundamental\\_rights.html](http://www.citizensinformation.ie/en/government_in_ireland/irish_constitution_1/constitution_fundamental_rights.html) , 7 March 2018.

<sup>78</sup> *Tartuntatautilaki*. §47-49. (21 December 2016)

<sup>79</sup> *Ibid.*

<sup>80</sup> Referendum. Finland (2018). Accessible: <https://www.kansalaisaloite.fi/fi/aloite/2636> , 10 January 2018.

vaccines and their possible side-effects. This is guaranteed on the Article 19 of the Universal Declaration of Human Rights.

The reason behind healthcare workers' mandatory vaccinations is the fact that the healthcare staff often encounters patients that do not have a normal immune system and their life can be endangered if they catch a disease, such as influenza.<sup>81</sup> Patients must be able to trust that their environment and their healthcare facilities are safe and therefore it is concerning that not all of the workers are immunized. Up to 25% of unimmunized workers develop influenza during the winter and the disease may even be asymptomatic.<sup>82</sup> As the influenza is very common and healthcare workers carry a higher-than-usual risk to get infected, the importance of collective immunization is therefore emphasized.

In the United States, the problem with mandatory influenza vaccinations takes another aspect when it comes to the federal legislation on protecting employees' medical records.<sup>83</sup> There is also the issue of discrimination, which an employer is not allowed to cause under any circumstances.<sup>84</sup> If, for some reason, the worker is not able to receive the vaccination, they are required to wear a mask during the flu season from November to March and this policy has been criticized for being discriminatory towards certain workers who are allergic or have other pressing reasons not to receive the vaccine.<sup>85</sup> Also, since the privacy of the workers' medical records is shared with the employer and is also clearly visible to all the patients, this has caused distress and a sense of humiliation amongst the health care workers.<sup>86</sup> The healthcare staff is leaning on Article 7 of the Universal Declaration of Human Rights and saying that these practices are discriminatory measures prohibited by said article. In the EU, the problem with health care workers' private medical records has also been discussed since due to the mandatory vaccination policies the private health information must now be shared with the employer and the rules of European data protection law must be

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<sup>81</sup> Hofmann, F., Ferracin, C., Marsh, G. et al. (2006). Influenza Vaccination on Healthcare Workers: A Literature Review of Attitudes and Beliefs. *Springer Link*. Volume 34, Issue 3. p. 142-147.

<sup>82</sup> *Ibid.*

<sup>83</sup> Kenyon, A. (2017). *Legal and Ethical Problems with Mandatory Vaccine Policies in the Workplace*. Kindle edition. United States: Pronoun.

<sup>84</sup> *Ibid.*

<sup>85</sup> *Ibid.*

<sup>86</sup> *Ibid.*

followed in these cases.<sup>87</sup> The EU legislation sets out rules on how to process data and the processors of data must also keep the data confidential.<sup>88</sup>

### 3.3 Informed consent

Patients have a right for autonomy of their medical decisions and the procedure but another important matter of discussion is the body integrity of patients and the informed consent patients must give prior to their procedures.<sup>89</sup> This consent, however, is not completely absolute since there are exceptions made if the patient is not able to give their consent due to a life-threatening condition, unconsciousness or other similar factor.<sup>90</sup> There are two different outlooks on consent: informed and voluntary ones.<sup>91</sup> The informed consent can be given in an expressed or implied manner and the expressed one can be given either in writing or verbally, whereas the implied consent can be given through actions, writing or circumstantially.<sup>92</sup> An informed consent refers to a consent that is given after the patient receives all the relevant factors, information and hears of the possible risks or side-effects and if this is not done adequately, the consent cannot be considered legally valid.<sup>93</sup> The European Union Charter of Fundamental rights Article 3 concerns the right to the integrity of a person and states that in the medical field a free and informed consent must be particularly respected. The Charter enjoys the same fully binding status in EU legislation as the EU Treaties do.<sup>94</sup> Often the validity of the consent is also evaluated by the reasonability of it. In the US legislation, for example, a valid consent is determined by an objective test evaluating, if all the relevant material and special risks are known to the patient, will a reasonable average person still consent to this type of a procedure.<sup>95</sup>

Informed consent is important when it comes to vaccinations as well since there are known side-effects to almost any vaccine regardless of whether the side-effect is grave or a minor symptom or a mere inconvenience. The issue with the consent in cases of mass immunization lies on the fact

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<sup>87</sup> Publication House of the European Union (2014). *Handbook on European Data Protection Law*. p. 170-173.

<sup>88</sup> *Ibid.*, p. 93.

<sup>89</sup> Arboleda-Florez, J. (1987). Reibl v Hughes: The Consent Issue. *The Canadian Journal of Psychiatry*. Volume 32, issue 1. Pages 66-70.

<sup>90</sup> *Ibid.*

<sup>91</sup> Diodati, C. (1999). *Supra nota* 6. p.144-165.

<sup>92</sup> *Ibid.*

<sup>93</sup> *Ibid.*

<sup>94</sup> Craig and De Búrca. (2015). *EU Law*. (Sixth Edition). Oxford University Press. p. 390.

<sup>95</sup>. Diodati, C. (1999). *Supra nota* 6.

that quite often the vaccination campaigns are supported by major state institutions and health organizations, and therefore individuals accept immunization as a self-evident procedure, rather than question it and this may lead to a vaccination culture where the health care workers in general already presume that the patient knows enough about the vaccine.<sup>96</sup> In these cases the way the information is distributed to the patient, such as an information leaflet, might not be sufficient.<sup>97</sup> The issue of neglect with individual and family medical history is also easy to pass during mass vaccination campaigns and a written consent is often accepted as an informed consent even if the patient is not aware of all the material and special risks.<sup>98</sup>

The case of *Hopp v Lepp* in 1980 focused on the problem of informed consent.<sup>99</sup> The appellant was an orthopedic surgeon and sued for battery and negligence on the basis that the written consent the patient had given prior to the operation was not an informed consent and lead to permanent physical damage of the patient.<sup>100</sup> The court held that the appeal should be allowed and the patient claimed damages for 15,000 Canadian dollars. A similar case that was held in the favor of the patient was the *Reibl v Hughes* case where the court held that even if there is only a small possibility of a certain risk, it must be told to the patient before the consent can be considered legally valid.<sup>101</sup> In the *Reibl v Hughes* case the main issue was that the patient had formally, but not with full knowledge of the possible material risks, consented to the procedure which then caused permanent damage and made the patient permanently disabled.<sup>102</sup> If a similar risk is associated with vaccines, people demand to be able to assess all the risks and therefor mass-vaccinations often neglect the procedure of informing the patient due to the lack of time and resources.

Body integrity and the value of an individual, as well as the importance of the free and informed consent is also considered in the Convention for the Protection of Human Rights and Dignity of the Human Being with regards to the Application of Biology and Medicine of 1997. The European Court is also the interpreter in this Convention. The Convention and its outlook sides more with those who are against the idea that mandatory vaccinations must be enforced over the public opinion in order to benefit the interest of the state. Article 2 of said Convention expresses the primacy of the human being over the interest of the state or science. The Article 5 states that an intervention

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<sup>96</sup> *Ibid.*

<sup>97</sup> *Ibid.*

<sup>98</sup> *Ibid.*

<sup>99</sup> Supreme Court of Canada, 2 S.C.R 192, 20.05.1980, *Hopp v Lepp*.

<sup>100</sup> *Ibid.*

<sup>101</sup> Supreme Court of Canada, 2 SCR 880, 07.10.1980, *Reibl v Hughes*.

<sup>102</sup> *Ibid.*

in the health field may only be carried out if there is free and informed consent. The interest of the state is clearly mass-immunization that prevents disease outbreaks and also makes the healthcare of the state less costly. The interest of science, on the other hand, lies within the comparative data produced by a properly immunized versus a non-immunized society or a group of people. The interest of an individual is undoubtedly the ability of impacting health-care decisions that are made concerning them. In this sense the legislation of the state and the perspective of people might conflict.

### 3.4 Aspects of globalization

Globalization imposes a challenge on human rights.<sup>103</sup> With globalization we are referring to the transformation of the world economy and mobility: reduction of barriers of trade, multinational enterprises, mobility of people in forms of migration and travel, economic integration and several international agreements promoting enhanced integration and sense of a community.<sup>104</sup> With the different aspects of globalization it is easier than ever to see the different statuses people have in regards to their possibilities of work, education and healthcare.<sup>105</sup> Especially the right to protection of health and right to an adequate standard of living are seen in a different light than before.<sup>106</sup>

With the fast-moving globalization it is essential that there are international organizations and movements promoting the same kinds of opportunities for all people.<sup>107</sup> The World Health Organization, UNICEF and International Center for Human Rights are on the forefront of establishing equal opportunity to all people regardless of their status, nationality, health, age et cetera.<sup>108</sup> It must be noted that when people, and especially when workers move from one country to another, they may be exposed to a different kind of legislation than in their home country and may need help fulfilling the requirements of their new country in various fields.<sup>109</sup> A good example of this is the health care providers' requirements in Finland or Latvia where the workers, who are in

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<sup>103</sup> Symonides, J. (1998). *Human Rights: New Dimensions and Challenges*. First edition. The United Kingdom: Ashgate Publishing Company.

<sup>104</sup> *Ibid.*

<sup>105</sup> *Ibid.*

<sup>106</sup> *Ibid.*

<sup>107</sup> *Ibid.*

<sup>108</sup> *Ibid.*

<sup>109</sup> *Ibid.*

charge of vaccinating others, have mandatory vaccination policies to follow themselves.<sup>110</sup> A migrant worker that does not have sufficient immunization will be immediately excluded from the possible workforce of such country. Thus far the states are not required to provide needed immunization for these foreign workers, which then puts them in an unequal position compared to the domestic job seekers.<sup>111</sup>

Extreme poverty and the exclusion of people are said to be great threats to humans rights.<sup>112</sup> Extreme poverty easily leads to exclusion from the rest of the society and yet, being a dynamic part of a society is regarded to be essential for normal human functioning and dignity.<sup>113</sup> The World Summit of Social Development recognized poverty to be a danger to ethical, social and moral aspects of human life.<sup>114</sup> The Article 2 of the Universal Declaration of Human Rights also states that no discrimination to the articles of the Declaration is allowed on the basis of any quality relating on the person in question and in this listing, property is also mentioned. Basically, this means that a lack of property and resources that the person has, cannot be used as a tool of discrimination. This can also be extended to the immunization of the person, since in many societies, a person that has not received adequate immunization can be excluded from state institutions, such as schools, and this is supported and mandated by legislation.<sup>115</sup> States do not necessarily offer free healthcare, nevertheless free vaccinations, and in this sense not everyone has access to the needed immunization. This is putting people in a discriminatory and an unequal position based on the fact of not having the necessary funds to get the needed vaccinations.<sup>116</sup> Right to education is also guaranteed by the Article 26 of the Universal Declaration of Human Rights. Therefore, if states are to enforce mandatory vaccination policies, it is imperative to offer the vaccinations for a very low cost or free of charge. If an incapability or refusal of mandatory vaccinations leads to consequences that are inclined to place people in an unequal or discriminative position, this is clearly against the Declaration and the rule of non-discrimination.

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<sup>110</sup> Haverkate, D'Ancona, Giambi, et al. (2012). *Supra nota 4*.

<sup>111</sup> *Ibid.*

<sup>112</sup> Symonides, J. (1998). *Supra nota 102*.

<sup>113</sup> *Ibid.*

<sup>114</sup> *Ibid.*

<sup>115</sup> Haverkate, D'Ancona, Giambi, et al. (2012). *Supra nota 4*.

<sup>116</sup> *Ibid.*

### 3.5 Right to Privacy of medical records

The medical records of patients contain data that needs protection. Not every patient can be assumed to give consent to the government to examine their medical history records and concurrently monitor, whether you have followed through with a vaccination program as expected. There is always a fear that the boundaries between an autonomic and a surveillance-state fade and the state is allowed to penetrate the boundaries of privacy in very delicate matters, such as medical records. In a global sense the current development of technologies is referred to as “the emerging global information society”.<sup>117</sup> It is clear that there are pressing requirements to protect electronic privacy and confidentiality.<sup>118</sup>

Article 8 (1) of the European Data Protection Directive qualifies medical data as sensitive data that enjoys special protection. If a mandatory vaccination policy is enforced, this will require a lot of processing of medical data and wide registries that need plenty of protection. Data Protection is fundamentally connected to human rights since the Article 8 of the European Convention on Human Rights provides “respect for private and family life, his home and his correspondence”. Therefore mandatory vaccination regimes and door-to-door vaccination programs have caused tremendous outrage.<sup>119</sup> During door-to-door vaccinations the health care providers have the immunization records of patients and they visit the patients’ homes providing vaccinations.<sup>120</sup> From the perspective of patients, these campaigns not only invade the privacy of their home, but also show a lack of respect towards the exclusivity of their family life and definitely breach the Article 8.

The issue of mandatory vaccinations and the way states inform one another in cases of foreign citizens’ medical records is especially prominent in the case of migrant workers and students that move in to a foreign country. Their immunization must also be established and maintained according to the law, but this requires that the state officials of the receiving state are given the medical records of the migrants. The Directive 95/46/EC handles the issue of cross-border data flow and the individual’s rights when it comes to protecting the rights of an individual in data processing.<sup>121</sup>

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<sup>117</sup> Symonides, J. (1998). *Supra nota* 102.

<sup>118</sup> *Ibid.*

<sup>119</sup> Kitta, A. (2012). *Vaccinations and Public Concern in History. Legend, Rumor and Risk Perception*. 1<sup>st</sup> edition. New York: Routledge.

<sup>120</sup> *Ibid.*

<sup>121</sup> The Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with the regard to processing of personal data and on the free movement of such data.

Third-country data flow is prohibited if the level of protection is not adequate under the section 57 of the preamble of the directive. This imposes a challenge on the national medical registries and the way they manage the private information on the immunization of their data subjects. This also means that the data subject must be notified in an adequate manner if the data is shared with a third-party and sufficient measures to protect the privacy have to be established both nationally and internationally.

The EU Directive also sets out elements that are required to be fulfilled by the data subject before the consent to use their private data can truly be considered as a valid consent.<sup>122</sup> Firstly, the data subject must be informed of what data is going to be used and what the consequences of consenting are.<sup>123</sup> The data subject must give a free consent without any outside pressure and the scope of the consent must be fully clear and disclosed to the data subject giving their consent.<sup>124</sup> Would this element of consent be a valid base for citizens that are anti-vaccine to forbid the use of their data in monitoring their immunization records? If so, the contrast between the interest of an individual and the benefit of the state is indisputably present.

In the medical field there are databases that are used as automated immunization tracking systems.<sup>125</sup> The idea behind such system is to replace personal immunization records that can be lost and instead provide a simple way for health care workers to access all necessary information regarding immunization.<sup>126</sup> This could, in fact, be a simple solution and much more efficient than the current tracking systems used, but the issue behind these kinds of databases is the disclosure, use and protection of private medical data.<sup>127</sup> The agencies which can utilize and process this data have to be carefully protected from information breaches and hackers.

If mandatory policies are enforced this needs a special registry of the patients' medical records that needs great protection. Can this kind of monitoring be required regardless of the patients' country and nationality and are the national authorities in international cases required to give up the personal data for the purpose of monitoring immunization?

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<sup>122</sup> Publication House of the European Union (2014). *Supra nota*. 83 p. 55-60

<sup>123</sup> *Ibid.*

<sup>124</sup> *Ibid.*

<sup>125</sup> Diodati, C. (1999). *Supra nota* 6. p. 236-237.

<sup>126</sup> *Ibid.*

<sup>127</sup> *Ibid.*

## 4. FAMILY LAW AND VACCINATIONS

### 4.1 Right to family life

The issue of mandatory immunization must be analyzed from three different perspectives. Firstly, by examining the family as a unit protected by legislation and whether states have a premise to interfere in the functioning of such unit. Secondly, the legal and social rights of a child must be taken into consideration. The third aspect is the legal responsibility that parents bear when it comes to the well-being of their children.

The respect to family life is determined in Article 8 of the European Convention on Human Rights and privacy is mentioned in the same article. Family life in general is a very broad concept and one must think of the parental responsibility, the welfare of the child and the family as a unit that can make distinctive decisions to have such a quality and way of life as they themselves wish without anyone interfering. Overall, the concept of protecting family life is interchangeable with family law and the human rights law since the protection is the key element in both of the cases. Applied to immunization, the question arises, whether the family as a functioning unit is challenged if there is plenty of state interference when it comes to the health care and immunization decisions made within the family for ethical, moral or religious reasons? Freedom of religion is expressed clearly in Article 18 the Universal Declaration of Human Rights as well. What are the proportionate measures state can use to interfere? The right to private life is a fairly broad concept and it does not only extend to privacy of information or data but also a person's moral and physical integrity.<sup>128</sup> This means that compulsory medical examination and treatment has to be protected by Article 8 and relates to the issue of body integrity and autonomy.<sup>129</sup>

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<sup>128</sup> Roagna, I. (2012). Protecting the Right to respect for private and family life under the European Convention of Human Rights. *Council of Europe Human Rights handbook*. Strasbourg.

<sup>129</sup> *Ibid.*

The European Court received a case (47621/13) in which the Strasbourg Court asked whether an obligation to vaccinate and sanctions taken against parents that refuse to vaccinate would be against the family freedoms of article 8 and 9 of the Convention and article 2 of Protocol No.1 to the Convention or the freedom of conscience? The sanction against the parents and the unvaccinated children was denying them access to school. Article 2 of the Protocol expresses that no person shall be denied the right to education and that it should be given respecting the parents' religious and philosophical convictions. The view of European Centre for Law and Justice concluded that the legitimate aim sought by compulsory vaccination must be reached in a way that is more respectful of moral and physical integrity of persons and the fundamental rights of parents and children.<sup>130</sup> The International Covenant on Economic, Social and Cultural Rights also mentions family in Articles 9 and 10. In these articles family is treated as a fundamental unit of society and therefore it needs security and protection.<sup>131</sup>

## 4.2 Parental responsibility

The House of Lords of the United Kingdom has stated that it is the right of parents to state their wishes in matters concerning the child even if the standpoint of the parents would not be the best regarding all the facts of the situation.<sup>132</sup> This, of course, does not mean that the opinion of the parents is always decisive but simply that it must be taken into account. The welfare principle is said to be detrimental and prevails over any other principle when concerning rights regarding children.<sup>133</sup> This concept of welfare is seemingly agreed upon everywhere, but can it be translated into achieving the welfare of a child via immunization?

Almost every country legislates the most important parental responsibilities. The United Kingdom especially states that a parent is responsible for agreeing to the child's medical treatment but do not demand mandatory vaccinations.<sup>134</sup> Finland demands parents to provide children preventing

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<sup>130</sup> Puppink, G. (2017). *Supra nota* 54.

<sup>131</sup> Rehman, J. (2003). *International Human Rights Law. A Practical Approach*. First edition. England: Pearson Education Limited.

<sup>132</sup> Scherpe, J. (2016). *European Family Law. Family Law in a European Perspective*. Third edition. United States: Elgar Publishing House. p. 228.

<sup>133</sup> *Ibid.*

<sup>134</sup> Gov.uk. (2018). *Parental Rights and Responsibility*. Crown Copyright. Accessible: <https://www.gov.uk/parental-rights-responsibilities> , 7 April 2018

care and child welfare and mentions prenatal and child health clinic services as well as other healthcare services.<sup>135</sup> The Netherlands also legislates parental responsibility, but on the other hand makes a distinction at the age of twelve: a child who is over twelve years old can request a medical treatment without parental consent.<sup>136</sup> In the US the capacity of the parents to provide a safe home with adequate food, clothing and medical care is listed as a factor that courts must consider when determining the best interest of a child.<sup>137</sup> In the 1960s it was considered a legal responsibility of parents to vaccinate their children not only for private, but also for the public benefit.<sup>138</sup> Guarding the health of a child was evidently acknowledged as an unquestionably important aspect of parental responsibility and this aspect was extended to immunization as well. Nowadays the controversy around vaccines has shifted the conversation towards two different directions: others think it is an essential part of parental responsibility to vaccinate children and others think they are best protecting the child by deciding not to vaccinate.

The 1989 Convention on the Rights of the Child provides another perspective on the benefit of children and grants them special protection, mentioning especially the right of a child to receive protection and health care. The Convention also mentions the parental duties and notes that the parental responsibility must be taken in to account when it comes to a child. The World Health Organization has established a Vaccine Security Strategy and the aim of this is to provide both accessible and safe vaccines to children around the world.<sup>139</sup>

The parental responsibility is also very closely connected to the European Convention on Human rights and the Article 8 that guarantees the right to private and family life without state interference. There are both rights and obligations when it comes to parenthood and the way in which parents look after their children. The controversy is that the parents have the obligation to put the child's benefit before own interest and on the other hand, they have the right to have a decisive impact on the treatments the child goes through.<sup>140</sup> Preventing serious diseases can be treated as an obligation and yet, the parents that oppose the immunization of their child, have the right to do

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<sup>135</sup> Lastensuojelulaki, 417/2007, §3 (2)

<sup>136</sup> Boele-Woelki, K., Schrama, W., Vonk, M. (2016). *Parental Responsibilities National Report – The Netherlands*. Accessible: <http://ceflonline.net/wp-content/uploads/Netherlands-Parental-Responsibilities.pdf> , 1 March 2018.

<sup>137</sup> Child Welfare Information Gateway. (2016). *Determining the Best Interests of the Child*. Accessible: [https://www.childwelfare.gov/pubPDFs/best\\_interest.pdf](https://www.childwelfare.gov/pubPDFs/best_interest.pdf) , 19 January 2018.

<sup>138</sup> Allen. (2007). *Supra nota* 3. p.17.

<sup>139</sup> Davey, S. (2009) *State of the World's Vaccines and Immunization*. Geneva. World Health Organization. p.22

<sup>140</sup> Scherpe. (2016). *Supra nota* 132.

so, and therefore these two factors collide. Whether a law has the right to determine this further and whether the state has a right to interfere is widely argued.

The concept of vaccine refusal is nowadays more recurrent in the pediatricians' daily life than ever before.<sup>141</sup> Parents either refuse to vaccinate their children, are concerned about the safety of vaccinations or in some countries, are outraged by the fact that some vaccines are mandatory. Even though the recent outbreaks of measles, pertussis and tuberculosis are confirming the concern that a lowered level of immunization proposes a risk, some still insist that the risk of immunization is greater than non-immunization.<sup>142</sup> There is also a social aspect to the pattern of the refusals. The most refusals come firstly from well-educated and wealthier white families and secondly from poor less-educated black families for different reasons.<sup>143</sup>

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<sup>141</sup> Leib, S., Liberatos, P., Edwards, K. (2011). Pediatricians' Experience with a Response to Parental Vaccine Safety Concerns and Vaccine Refusals: A Survey of Connecticut Pediatricians. *Public Health Reports*. Vol.126 (Suppl.2), 13-23.

<sup>142</sup> *Ibid.*

<sup>143</sup> *Ibid.*

## 5. VACCINE LIABILITY

### 5.1 Vaccine safety

One of the most important landmark cases was the *N.W. et al. v. Sanofi Pasteur MSD*, C-621/15 case concerning vaccination manufacturers' liability.<sup>144</sup> In this case it was concluded that the liability of the manufacturer, even if it could not be proven by medical research but rather "serious, specific and consistent evidence" was aligned with the European law of products liability.<sup>145</sup> Every case must be examined separately and as the Article 4 of the Council Directive 85/374/EEC states the injured person has the burden of proof relating to defect and damage.<sup>146</sup> A proven causal link is also needed. The key element of the Court's decision was that in order for the lawsuit to serve action the plaintiff must prove the defect in the vaccination.<sup>147</sup> This decision sparked some criticism in the public. It could be worrying to the consumer that if a vaccination, in fact, does have a defect in it and leads to injury, they first have to challenge a powerful medical company and secondly acquire evidence against it. This could be distressing regarding the person's legal protection and abilities to protect themselves.

A vaccine is only successful if it is to be trusted. As public health greatly relies on the decisions made by the public to immunize or not, it is essential that the public is confident that the vaccination is safe and secure to use.<sup>148</sup> There is always the skepticism that implies big vaccine manufacturers are only aiming for maximizing profit on vaccine sales, but in these cases, the government

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<sup>144</sup> Judgment of the European Court of Justice. C-621/15. (7.11.2017)

<sup>145</sup> Stein, A. (2017). Vaccine Liability in Europe: A New Development. *Harvard Law Petrie-Flom Center*.

<sup>146</sup> Council Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products. (25 July 1985).

<sup>147</sup> *Ibid.*

<sup>148</sup> Allen. (2007). *Supra nota 3*, p.21.

must be able to show why obtaining the vaccine is demanded from people to further better public health on a wide scale.<sup>149</sup>

In the United States the decisions on vaccine safety and liability lean on the 1986 National Childhood Vaccine Injury Act.<sup>150</sup> The act defines the National Vaccine Program that has objectives in the fields of vaccine research, safety and development.<sup>151</sup> There are some fundamental differences between the liability issues of European Union and the United States.<sup>152</sup> In the US there is a special Vaccines Court and all vaccine claims are also managed by Office of Special Masters within the US Court of Federal Claims.<sup>153</sup> The Vaccine Court serves to compensate people whose evidence clearly shows an injury, disability or death is linked to vaccinations.<sup>154</sup>

Unlike the *N.W. et al. v. Sanofi Pasteur* decision leaning on causal link concluded, having already accustomed to in the European legislation, the system in the US leans on medical proof. The requirement states that medical proof must be presented when prosecuting against the vaccine manufacturer.<sup>155</sup> The Vaccine Court then has to conclude that the vaccine was detrimental in afflicting the injury. There is a risk-utility test developed by professor John Wade that is used to determine whether the plaintiff can be given compensation for the injuries and whether the liability lies on the manufacturer.<sup>156</sup> The National Vaccine Injury Compensation Program began in 1988 in the US and since then, more than 3,18 billion dollars have been awarded to families who claim a vaccine has caused some harm.<sup>157</sup>

The controversy concerning vaccinations' link to autism is still one of the most known debates within the medical field.<sup>158</sup> After 1980 diagnosed autism cases in the US were on the rise and this was at a time when mass-immunization campaigns were targeting children and young adults, and entering 1999 there had been more than five thousand claims arguing the measles-mumps-rubella

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<sup>149</sup> *Ibid.*

<sup>150</sup> Institute of Medicine (US) Committee on Review of Priorities in the National Vaccine Plan. (2010). *Supra nota* 16.

<sup>151</sup> *Ibid.*

<sup>152</sup> Stein, Alex. (2017). *Supra nota* 143.

<sup>153</sup> Office of Special Masters. (1986). *The National Vaccine Injury Program*. Pub. L. No. 99-660, 100 Stat. 3755.

<sup>154</sup> Health Resources & Services Administration. (2018). *National Vaccine Injury Compensation Program*. Accessible: <https://www.hrsa.gov/vaccine-compensation/index.html> , 1 May 2018.

<sup>155</sup> Judgment of the European Court of Justice. C-621/15. *N.W. et al. v. Sanofi Pasteur*. (7.11.2017)

<sup>156</sup> Epstein, R. (1987) "The Risks of Risk/Utility". *48 Ohio State Law Journal*, 469.

<sup>157</sup> Health Resources & Services Administration. (2018). *Supra nota* 152.

<sup>158</sup> Haertlein, L. (2012) Immunizing Against Bad Science: The Vaccine Court and the Autism Test Cases. *Law and Contemporary problems*. Vol. 75:221.

vaccine had caused autism among children.<sup>159</sup> This was speculated in an article in the *Lancet Journal* by British physician Andrew Wakefield who criticized that the vaccination program was widely targeted at children but not properly tested. This, of course, caused outrage in the public and drove even public figures such as Senator Robert Kennedy and actress Jenny McCarthy to assert the issue in public forums.<sup>160</sup> Following this, however, after intensive examination it was concluded that there was no real proof of a link between vaccinations and autism.<sup>161</sup> Therefore a liability could not be deducted from the claims.

Aside from autism, and multiple sclerosis, post-vaccination seizures are also a majorly debated subject regarding childhood vaccinations.<sup>162</sup> It is argued, that vaccinations and more precisely, the timing of childhood vaccinations would have a causal link to seizures that vaccinated children are experiencing. A study prepared by the American Academy of Pediatrics analyzed the data gathered of 323,247 US children in the years 2004 to 2008 and found no association between the timing of childhood vaccinations and seizures.<sup>163</sup>

### 5.3 Insurance

There is a plethora of questions relating to parental responsibility when pondering whether to vaccinate a child or not. A question is also risen within the insurance companies' policies. Whilst contacting Finnish insurance companies on their views on vaccinations that are listed in the Finnish vaccination policy it can be concluded that the views of the insurance companies were neutral concerning vaccination.

The insurance company Fennia through their representative Maija Miettinen stated that if a child is treated because of an illness that could have been prevented with the vaccination, the insurance company Fennia will still bear the costs and the treatment falls within their insurance policy.<sup>164</sup>

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<sup>159</sup> Andrew J. Wakefield. (1999) MMR Vaccination and Autism. *The Lancet Journal*. Volume 354, No 9182. P. 949-950.

<sup>160</sup> Haertlein, L. (2012). *Supra nota* 158.

<sup>161</sup> *Ibid.*

<sup>162</sup> Hambidge, S., Newcomer, S., Narwaney, K. *et al.* (2014). Timely Versus Delayed Early Childhood Vaccination and Seizures. *Pediatrics*. Vol 141. Issue 5.

<sup>163</sup> *Ibid.*

<sup>164</sup> Maija Miettinen. Insurance Expert. Aino Ukkonen. E-mail interview with Fennia Insurance. 10/2017.

The parental decision of not to vaccinate does not influence the indemnity received from the insurance company. The life insurance department and their representative, on the other hand, stated that when applying to a life insurance the patient records concerning vaccination history is not asked nor demanded and therefore does not affect indemnity for customers from 15 to 75 years old that are eligible to apply for a life insurance. Life insurance is not possible to apply for children under the age of 15.<sup>165</sup>

Another contacted insurance company IF and their representative Piia Kononen did not take a stance concerning vaccinations or the lack thereof. Her statement declared that for their indemnities they follow the Finnish legislation and it would not, in practice, be possible to treat customers differently based on the fact whether they have been vaccinated or not.<sup>166</sup> It is not mandatory to vaccinate children in Finland and there is no mandatory vaccination policy.<sup>167</sup> If a person is treated for a disease that could have been prevented by a vaccination the customer is still entitled to an indemnity. Her statement was concluded with the notion that at the moment the conversations regarding vaccinations and insurance policies are outside the scope of what insurance companies can decide in their policies and therefore a link between the immunization of a person and the insurance policy that can be offered cannot be established.<sup>168</sup>

If there is a mandatory vaccination policy in the state in which the insurance is provided, can the stance of insurance companies then change? For example, could it be possible in the future that insurance companies list in their terms and conditions of the insurance contract that the customer must be vaccinated? Would this kind of access to personal immunization records be a violation on the privacy of sensitive medical data and would it be defensible against human rights law to discriminate their clients on the basis of immunization or the lack thereof? Most likely the insurance companies will be able to set such terms and conditions since they have to assess their own risk in order to make sensible contracts with the clients.

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<sup>165</sup> *Ibid.*

<sup>166</sup> Piia Kononen. Head of product development. Aino Ukkonen. E-mail interview with IF Insurance. 10/2017.

<sup>167</sup> EFVV European Forum for Vaccine Vigilance. (2018). *Vaccines and Vaccination Freedom of Choice*. Accessible: <https://www.efvv.eu/finland-2/>, 9 January 2018.

<sup>168</sup> Piia Kononen. 10/2017. *Supra nota* 162.

## CONCLUSIONS

In this thesis the author has examined different legal aspects of enforcing mandatory vaccination policies and whether a mandatory policy can be justified according to human rights law, family law and the aspect of privacy and body integrity. The transition of vaccines from an experimental new invention to an immunization regime mandated by law is one of the greatest and most controversial medical developments of all time.

The body integrity and the ability to make decisions concerning own medical procedures, including vaccinations, is supported by human rights law and the first important step is to have the free and informed consent of the patient.<sup>169</sup> Informed consent is especially protected by the European Union Charter of Fundamental Rights. Article 3 concerns the right to the integrity of a person. Mass-immunization regimes are severely criticized for not being able to provide all the information on the risks of the vaccines to the patient and therefor Article 3 is breached. If a person is against the mandatory vaccine, protection can be sought from Article 3. The Convention for the Protection of Human Rights and Dignity of the Human Being with regards to the Application of Biology and Medicine of 1997 also protects the aspect of consent. Article 5 of this Convention states that procedures can only be followed through if there is free consent and so there is controversy between following the Convention and enforcing a mandatory vaccine. Article 2 on the other hand states that the right of an individual must always be protected over the interest of science. It could be concluded that the right to body integrity is more prominent than the mandatory policy of the state.

There is always a risk of placing people in a discriminatory position if people are categorized into

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<sup>169</sup> Arboleda-Florez, J. (1987). *Supra nota* 95.

immunized and non-immunized. Discrimination is prohibited in the Universal Declaration of Human Rights Article 7 and all people must be granted the same protection under law. The reasons behind not being able to vaccinate can be numerous and depending on multiple different factors, including lack of monetary funds or being a foreign national, and therefore limiting those who are not able to get the proper vaccinations is against the Article 2 of the Universal Declaration of Human Rights, which grants everyone the same rights and freedoms regardless of origin, property or status. In the most extreme cases a person who is not immunized may be excluded from state institutions, such as schools. This type of exclusion is directly against the Article 13 of the International Covenant on Economic, Social and Cultural Rights which guarantees everyone the right to education and also the Article 26 of the Universal Declaration of Human Rights which states the aforesaid. Basis of an adequate healthcare stems from Article 25 of the Convention and mothers and children are especially protected.

In this sense the state breaches the individual's rights of body integrity and human rights by enforcing mandatory vaccination policies. However, Article 12 of the International Covenant on Economic, Social and Cultural Rights firstly guarantees that states must recognize the right of everyone to enjoy the greatest mental and physical health that is possible and an especially mentioned part of this is preventing and controlling disease.<sup>170</sup> All diseases controlled by vaccines are ones that have caused severe fatalities during the previous decades and are also highly infectious. Therefore it is essential that in order to protect people and following Article 12 the states enforce collective immunization.<sup>171</sup> Maintaining a vaccination policy is much more cost-efficient to states than treating infectious disease preventable by vaccines.<sup>172</sup>

The recurrence of diseases preventable by vaccines have never been as low worldwide but it is concerning that some outbreaks of disease are very recent due to a decreasing level of immunization.<sup>173</sup> Internationally, there are vaccination policies that are enforced in different ways: others are strictly mandatory whereas others are completely voluntary.<sup>174</sup> The way, in which states enforce their vaccination policies has raised a question regarding Article 8 of the European Convention on Human Rights. Article 8 provides respect for family life, privacy and correspondence and highly invasive mandatory or door-to-door vaccination regimes is clearly against the Convention.

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<sup>170</sup> Allen. (2007). *Supra nota 3*, p.17.

<sup>171</sup> *Ibid.*

<sup>172</sup> Maglione, M., Das, L., Raaen, L. et al. (2014). *Supra nota 11*.

<sup>173</sup> *Ibid.*

<sup>174</sup> Haverkate, M. et al. (2012). *Supra nota 4*.

The European Centre for Law and Justice have also given their opinion on the mandatory vaccination policies and possible penal consequences of refusing to vaccinate. Their perspective is that rather than enforcing a mandatory policy, the emphasis should be on informing citizens of vaccines and recommending the sufficient immunization.<sup>175</sup> Often refusing a vaccination stems from factors of a social status of the family.<sup>176</sup>

Family life and respecting the family as a unit also includes the freedom of the religion that the family practices. Article 18 of the Universal Declaration of Human Rights grants everyone the freedom of thought, religion and conscience. Therefore a family that refuses to follow through a mandatory vaccination regime for religious purposes should be allowed to do so. However, the problem once again lies on the fact that states have the responsibility of protecting their citizens and preventing disease and the way to do this is protecting the collective immunization.<sup>177</sup> Therefore states that do not accept religious reasons for vaccine refusal are allowed to enforce this even though there is a great controversy.<sup>178</sup>

Parental responsibility demands guarding the health of a child and the 1989 Convention on the Rights of the Child guarantees the right of a child to receive adequate healthcare and protection. Due to the empirical research on the benefits of vaccinations it can be said that protecting the child also means the proper immunization of the child.<sup>179</sup> The controversies of vaccines causing autism, seizures and multiple sclerosis have all been proven false.<sup>180</sup> Therefore the benefit of the vaccination is greater than non-vaccination and can be said to respond to the demands of the Convention on the Rights of the Child. As parents take care of the vaccinations of their own child, they also protect the health of other children and especially those whose immune system has been compromised or cannot be vaccinated due to other issues.

Many practices that states are following concerning mandatory vaccinations seem prone to weaken the protection of human rights of an individual. The risk of discrimination and inadequate protection before law poses a risk on states that decide to protect the collective health through mandatory immunization. The states, however, must follow their responsibility of protecting their citizens. It

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<sup>175</sup> Puppink, G. (2017). *Supra nota* 54.

<sup>176</sup> Leib, S., Liberatos, P., Edwards, K. (2011). *Supra nota* 139.

<sup>177</sup> Allen. (2007). *Supra nota* 3, p.17.

<sup>178</sup> Walkinshaw, E. (2011). *Supra nota* 48.

<sup>179</sup> Haertlein. (2012). *Supra nota* 158.

<sup>180</sup> *Ibid.*

could therefore be concluded that if certain exceptions are granted to people based on their convictions and if receiving vaccinations does not depend on social or financial status, a mandatory vaccination policy can be legally enforced in order to protect the collective immunization and it does not conflict with the human rights legislation. The mandatory regimes need to be carefully thought out and enforced with adequate respect towards people and their private lives. Enforcing a mandatory vaccination policy in a country where the compliance of the vaccinations is very good in general is not necessarily beneficial, and in this perspective, recommending the needed vaccines is more efficient than imposing strict mandatory rules.

In the author's opinion the collective immunity is taken for granted and therefore the recent outbreaks of diseases preventable by vaccines are not taken seriously or recognized as a threat to public health and safety. The public opinion seems to be based on emotion and rumors, rather than facts and research, and therefore it is understandable that states want to enforce mandatory vaccinations. The way in which vaccines are portrayed in media seems to always forget about the positive side and benefits of immunization and focuses on the negative side emphasizing the threat of a mandatory policy.

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