

TO VACCINATE OR NOT TO VACCINATE. BETWEEN MORAL AND CRIMINAL BOUNDARIES

Phd. Laura Stanila

Senior lecturer, Faculty of Law, West University, Timișoara, Romania

Contact: laura.stanila@e-uvv.ro.

Abstract

In the current social context, the issue of children's vaccination is a hot topic that has divided both public opinion and medical professionals into two belligerent camps that are fighting an endless war. The issue of vaccination can be approached from a multiple perspective but, by virtue of our specialization, we have proposed an objective approach that starts with morality and ends with the identification of legal boundaries, both in terms of the state's right to impose the vaccination of children, as well as the right of parents to refuse to execute such an obligation. Can we talk about a right and a correlated legal obligation in terms of child vaccination? What would be the rationale for editing imperative rules imposing such a task that can have consequences in terms of physical development, health of children and even their life? The act of criminalizing human behaviour must respect the desiderata of specific social peril level, necessity and proportionality. Is the penal intervention of the State on the issue of sanctioning the parents' refusal to vaccinate their children in accordance with these desiderata? Here are just a few of the ideas that we propose to discuss in the present study, which aims not to provide terse solutions, but to invite to an open, impartial and balanced dialogue.

Highlights

- Public misconceptions contribute to the maintaining of the conflict between pros and cons vaccine groups.
- National legislators have developed different type of rules in the area of medical law/vaccination: mandatory or permissive
- The necessity of ruling through criminal means in case of vaccine refusal is debatable.

Keywords: *vaccine, criminal liability, ethics, legal boundaries, proportionality*

Abbreviations

WHO - World Health Organization

SAGE - Strategic Advisory Group of Experts

IAC - Immunization Action Coalition, Minnesota USA.

MMR – vaccine for measles, mumps and rubella

BCG – vaccine for Bacillus Calmette-Guerin used to combat tuberculosis

TB – tuberculosis

DTP 1 – combined vaccine for diphtheria, pertussis and tetanus.

vs. – versus

art. – article

RCC – Romanian Criminal Code

HCC – Hungarian Criminal Code

a.n. - author's note

Contents

1. About the Ethics of Incrimination

2. About vaccination without prejudices. Definitions, numbers, facts, decisions

3. Draft law on vaccination voted by the Roman legislature and its controversies

4. To vaccinate or not to vaccinate vs. to incriminate or not to incriminate.

Moral and criminal boundaries

4.1. Penal boundaries

4.2. Ethical boundaries

5. Conclusions

1. About the Ethics of Incrimination

The reaction of the society against dangerous harmful individual conducts is a necessity dictated by the need to safeguard social order and the fundamental values protected by the rules of law. The passivity of society facing human behaviour that threatens the development of social relations could result in short, medium and long-term damage, could generate chaos.

We argued, for several times now¹, that the effective protection of the social values identified in the field of bioethics by means of criminal law is not a matter unanimously accepted in the literature. Some researchers think that certain areas of social life, such as human reproduction and vaccination, should be excluded from state protection by means of criminal law. It has been shown that the criminal law has an excessively severe and inflexible character, and because of its rigor it cannot keep up with the scientific progress whose results are so quick and surprising.

¹ Laura Stănilă, *Provocările bioeticii și răspunderea penală* (2015), București, Editura Universul Juridic, pp. 23-24; also see Laura Stănilă, *Principiul precauției și etica incriminării. O abordare bioetică* (2015) in D. Popescu, S. Rădulețiu (editors), *Conference Proceedings, Vol. 4, Post-Doctoral Research within Social and Humanistic Sciences*, Editura Alma Craiova, pp. 288-302.

Medical technologies, continuously developing, have generated and still generate fierce controversy in society, and a regulation by non-penal rules is preferable to excessive penal regulation that would require unanimous agreement.² The call for criminalization cannot be achieved as a solution to the lack of other viable legislative options. Criminal laws are strict, inflexible and time-consuming and are incapable of reflecting the diversity and complexity of ethical theories present at a particular moment in society, non-penal regulation being sufficiently flexible and effective in balancing the scientific development and constantly changing social priorities.³

The second doctrinal orientation highlights the need to criminalize these conducts occurred in the area of Bioethics, starting from the idea that avoidance or lack of criminalization conveys a message of tolerance and encouragement of such behaviours. The criminalization of a human conduct is the supreme indictment of the maximum importance of that specific conduct to society. Also, and a penal rule is able to be as flexible as a non-penal one, without hindering the progress of science⁴.

In every social context there are at least several controversial issues that tend to divide society in pros and cons groups. As long as there is no unanimous view or at least a significant majority of the expressed opinions, it is obvious that an attempt to protect a specific social value by means of criminal law appears to be excessive and unfair. The law, and in particular criminal law, is framed by religion and grounded on its principles. The two major models of criminal policy currently in existence - the repressive-authoritarian model and the liberal-preventive model - obviously provide opposite solutions to the question we are addressing: is criminalization an effective and useful to medical practice subject of bioethical concerns?

a)The repressive-authoritarian model has reappeared as a result of the proliferation of the criminal phenomenon in general. The number of crimes has increased, the level of seriousness of sentences has increased, reaching what has been called an "excess of incrimination" or overcriminalization. It has been shown that this excess of incrimination is evidence that society is constantly evolving.⁵

Other scholars have also shown that in particular fields of bio-medicine the excess of incrimination is not an exaggeration, but a path imposed by technical and

² T. Caulfield, L. Knowles, E.M. Meslin, *Law and Policy in the Era of Reproductive Genetics* (2004), in *Journal of Medical Ethics*, vol. 30: 2004, <http://jme.bmj.com/content/30/4/414.full?sid=c32779f1-8a54-4b71-b944-a5771774cd9e> (accessed 30.04.2018). also see: Alexandra Huidu, *Reproducerea umană medical asistată. Etica incriminării versus etica biologică. Studiu de drept comparat* (2010), Editura Lumen, Iași, pp. 125-128.

³ T. Caulfield *et al.* (2004), p. 133.

⁴ Laura Stănilă, *Principiul...*, p. 290.

⁵ Alexandrara Huidu (2010), p. 157.

scientific development that comes to counterbalance and reduce the impact of such tendencies.⁶

We do not share this view, the excess of criminalization being an over-reaction of society to a phenomenon that is hard to combat and control, but in the same time very difficult to define - criminality. It is a natural reaction based on fear, fear of escalation and chaos. This reaction is understandable, but undergoes beyond area of normality, since fundamental principles, essential for society and the rule of law are violated: the principle of proportionality, principle of minimum intervention, the principle of individual autonomy. These principles being breached, the desideratum of the common good that grounds any organized action loses its brilliance.

b)The liberal-preventive model is based on the idea that criminal justice should not only punish - "eye for eye, tooth for tooth, evil for evil" - but must prevent and educate, "to strike a balance between efforts to combat crime and the protection of individual rights and freedoms"⁷.

Why open a discussion on the question of vaccination in relation with the issue of criminalization? Because an increasing number of countries choose to regulate vaccination as mandatory, opening paths for some voices which sustain a penal intervention in case of vaccination refusal.

2. About vaccination without prejudices. Definitions, numbers, facts, decisions

A vaccine is a biological preparation that improves immunity to a particular disease. A vaccine typically contains an agent that resembles a disease-causing microorganism, and is often made from weakened or killed forms of the microbe, its toxins or one of its surface proteins. The agent stimulates the body's immune system to recognize the agent as foreign, destroy it, and "remember" it, so that the immune system can more easily recognize and destroy any of these microorganisms that it later encounters.⁸ The increasing globalization in the production and distribution of these biological medicines has opened new possibilities to better manage public health concerns, but has also raised questions about the equivalence and interchangeability of medicines procured across a variety of sources. International standardization of starting materials, of production and quality control testing, and the setting of high expectations for

⁶ Mark Brown, *The Politics of Penal Excess an the Echo of Colonial Penalty* (2002), in *Punishment and Society*, no. 4/2002, p. 411.

⁷ Jean Pradel, *Droit penal compare* (2002), 2eme edition, Dalloz, Paris, p. 154.

⁸ World Health Organization (WHO), *Definon of vaccine*, <http://www.who.int/topics/vaccines/en/> (accesed 28.04.2018).

regulatory oversight on the way these products are manufactured and used have thus been the cornerstone for their continued success. But it remains a field in constant change. The continuous technical advances in the field offer a promise of developing potent new weapons against oldest public health threats, as well as new ones - malaria, genetic deficiencies, pandemic influenza, etc. - but also put a great pressure on manufacturers, regulatory authorities, and the wider medical community to ensure that products continue to meet the highest standards of quality attainable.⁹

Vaccine production systems in general use are well established and include fermentation and the growth of viruses in cell culture. The use of recombinant DNA-based expression systems, such as yeast, is well established, and the regulatory issues associated with these systems have been considered in great depth over the years, with a clear product development pathway. There are numerous other possible production systems, however, including expression in insect cells (or living insects), in transgenic animals and plants expressing foreign proteins, or in other novel cell substrates, such as human tumor-derived cell lines. The benefit-risk evaluation for vaccines requires especially careful consideration giving the fact that they are medicines usually given to healthy individuals to protect against diseases that they may never develop. The acceptable level of risk and uncertainty is therefore very low, and the regulatory approach used is extremely conservative. Therefore, while novel production systems may each provide specific benefit over traditional ones, they must be evaluated carefully.¹⁰

In accordance with its mandate to provide guidance to Member States on health policy matters, WHO issues a series of regularly updated position papers on vaccines and combinations of vaccines against diseases that have an international public health impact. These papers are concerned primarily with the use of vaccines in large-scale national immunization programs. They summarize essential background information on diseases and vaccines and conclude with the current WHO position on the use of vaccines worldwide.¹¹

For example, Recommendation of WHO on the question if the BCG vaccine should be given to infants at birth or at the time of the first dose of the diphtheria tetanus and pertussis (DTP1) containing vaccine at 6 weeks of age to mitigate the

⁹ WHO, *Immunization standards*, http://www.who.int/immunization_standards/vaccine_quality/en/ (accessed 28.04.2018).

¹⁰ Lindsay Elmgrena, Xuguang Lia, Carolyn Wilsonb, Robert Ballb, Junzhi Wangc, Klaus Cichutekd, Michael Pflaidererd, Atsushi Katoe, Marco Cavalerif, James Southerng, Teeranart Jivapaisarnpongh, Philip Minori, Elwyn Griffithsj, Yeowon Sohnk, David Wood, *A global regulatory science agenda for vaccines*, in *Vaccine*, 2013, [Volume 31, Supplement 2](#): B163-B175, p. B166, https://ac.els-cdn.com/S0264410X12015939/1-s2.0-S0264410X12015939-main.pdf?tid=c0f4909a-5e97-4154-8917-53f9429a08c8&acdnat=1525087224_fff7f9ca967c6a06f6c73412bc15ffc8 (accessed 28.04.2018).

¹¹ WHO, *Weekly epidemiological record*, 23 February 2018, 93th Year, no. 8, 2018, 93, 73-96, <http://www.who.int/wer>, (accessed 28.04.2018).

risk of severe TB disease, with special focus on countries with a high burden of TB. WHO recommends in countries or settings with a high incidence of TB and/or leprosy, a single dose of BCG vaccine should be given to neonates at birth, or as soon as possible thereafter, for prevention of TB and leprosy disease. If it cannot be given at birth, it should be given at the earliest opportunity thereafter and should not be delayed. Any delay in vaccination may lead to opportunities for known or unknown exposure to TB or leprosy infected contacts. Co-administration of BCG with the hepatitis B birth dose is safe and strongly recommended. In order to avoid missed opportunities for neonatal vaccination, BCG multi-dose vials should be opened and used despite any wastage of unused vaccine. If the birth dose was missed, catch-up vaccination of unvaccinated older infants and children is recommended since evidence shows it is beneficial. Catch-up vaccination should be done at the earliest convenient encounter with the health-care system to minimize known or unknown exposure to TB or leprosy infected contacts.¹²

Vaccines can generally be co-administered (i.e. more than one vaccine given at different sites during the same visit). Recommendations that explicitly endorse co-administration are indicated in the table, however, lack of an explicit co-administration recommendation does not imply that the vaccine cannot be co-administered; further, there are no recommendations against co-administration (BCG, Hepatitis B, Polio, etc.). Other vaccines, such as varicella and pneumococcal polysaccharide vaccines, may be of individual benefit but are not recommended for routine immunization¹³.

Despite WHO recommendations and their obvious benefit for both public and individual health, the number of doses a child gets from birth to the age of 10 and some debatable side-effects are a question of maximum importance and a cause for fierce controversy both in public opinion and among scholars.

For example, according to IAC Minnesota USA, a child could get a minimum of 25 up to 30 doses of vaccine for several diseases¹⁴

In June 2012, a provincial court in Rimini, Italy granted compensation to the family of a child named Valentino Bocca. The family alleged that the MMR vaccine Valentino received as part of his childhood immunizations caused his autism, and the court compensated them on that theory. The lower court's decision was never on very firm grounds: it depended in part on testimony of an expert witness who relied on a debunked study written by Andy Wakefield. Unfortunately, this Italian

¹² SAGE *Evidence to recommendations framework*, Table 3 BCG vaccination at birth vs. at 6 weeks, p. 7, http://www.who.int/immunization/policy/position_papers/bcg_vaccination_birth_vs_6weeks.pdf?ua=1, (accessed 30.04.2018).

¹³ WHO *Recommendations for all immunization programmes, Table 1: Summary of WHO Position Papers - Recommendations for Routine Immunization*, p. 3, http://www.who.int/immunization/policy/Immunization_routine_table1.pdf?ua=1 (accessed 30.04.2018).

¹⁴ IAC Saint Paul Minnesota USA, *Vaccination for Infants and Children, Age 0-10 Years*, <http://www.immunize.org/catg.d/p4019.pdf> (accessed 30.04.2018).

MMR autism decision has been used by anti-vaccine activists as part of their claims that vaccines cause autism. On February 13, 2015, immunization rates in the province of Romagna The Court of Appeal accepted the appeal filed by the Ministry of Health. The expert appointed by the court of appeal highlighted that there is no scientific evidence supporting an MMR autism link. The expert highlighted that the lower court expert was wrong to rely on the study by Andrew Wakefield, a study debunked and rejected by the scientific community.¹⁵ Despite an impressive number of scientific studies¹⁶ demonstrating no connection between vaccines and autism, the public debate is in flames and showing no signs of abatement.

Another view on the problem is offered by some national courts which interpret the medical rules in connection with vaccination as mandatory, forcing parents to vaccinate their children against their will and believes: e.g. the case of a vegan mother who wanted her sons to live a "toxin free" life was forced to make them receive routine vaccinations after the High Court in UK overruled her objections.¹⁷ This is not the only available example. As a matter of fact there is an important number of court decisions imposing the vaccines as mandatory.¹⁸

The European Court of Justice has been accused of undermining Britain's vaccination program after ruling that patients can sue for illnesses they believe were caused by jabs, even when there is no scientific evidence.

¹⁵ Dorit Rubinstein Reiss, *Italian MMR Autism Decision Overturned*, article published on 20.12.2016 on skepticalraptor.com,

<https://www.skepticalraptor.com/skepticalraptorblog.php/italian-mmr-autism-decision-overturned/> (accessed 30.04.2018). See also http://www.repubblica.it/salute/medicina/2015/03/01/news/autismo_i_giudici_assolvono_il_vaccino-108441541/?refresh_ce (accessed 30.04.2018).

¹⁶ E.g. V. Demicheli, A. Rivetti, M.G. Debalini MG, C. Di Pietrantonj, *Vaccines for measles, mumps and rubella in children*, *Cochrane Database Syst. Rev.*, 2012 Feb 15; (2):CD004407. doi: 10.1002/14651858.CD004407.pub3, <https://www.ncbi.nlm.nih.gov/pubmed/22336803> (accessed 30.04.2018); F. Destefano, C.S. Price, E.S. Weintraub, *Increasing exposure to antibody-stimulating proteins and polysaccharides in vaccines is not associated with risk of autism*, *J Pediatr*. 2013 Aug;163(2):561-7. doi: 10.1016/j.jpeds.2013.02.001. Epub 2013 Mar 30, <https://www.ncbi.nlm.nih.gov/pubmed/23545349> (accessed 30.04.2018); K.M. Madsen, A. Hviid, M. Vestergaard, D. Schendel, J. Wohlfahrt, P. Thorsen, J. Olsen, M. Melbye, *A population-based study of measles, mumps, and rubella vaccination and autism*, *N Engl J Med*. 2002 Nov 7;347(19):1477-82. PubMed PMID: 12421889, <https://www.nejm.org/doi/full/10.1056/NEJMoa021134> (accessed 30.04.2018); D. Mrozek-Budzyn, A. Kiełtyka, R. Majewska, *Lack of association between measles-mumps-rubella vaccination and autism in children: a case-control study*, *Pediatr Infect Dis J*. 2010 May; 29(5):397-400. doi: 10.1097/INF.0b013e3181c40a8a. PubMed PMID: 19952979, <https://www.ncbi.nlm.nih.gov/pubmed/19952979> (accessed 30.04.2018); and so on.

¹⁷ Rachel Roberts, *Vegan mother forced by High Court to vaccinate her children*, article published in Independent UK on 6.04.2017, <https://www.independent.co.uk/news/uk/home-news/vegan-mother-vaccinate-children-high-court-toxin-free-kids-mmr-anti-vaxxer-a7670881.html>, (accessed 28.04.2018).

¹⁸ BBC News, *High Court orders two sisters must receive MMR vaccine*, article published on 11.10.2013, <http://www.bbc.com/news/health-24493422>, (accessed 30.04.2018).

The EU's highest court said on 21st of June 2017 that if a number of healthy people developed a disease shortly after receiving a vaccine then that would serve as enough proof to bring a claim.¹⁹

The ruling, which health experts in Britain said was of serious concern, opens the door for class actions from patients who believe their health was affected by vaccines, even when there is no medical proof.²⁰

The European court vaccine decision is – despite all the comments it led to – a decision that allows, even encourages, under specific presumptions, member states, in situations of scientific uncertainty in product liability – not just vaccines – to consider other factors, such as temporal proximity of harm to vaccine, and compensate a plaintiff even without clear scientific evidence supporting causation.²¹

3. Draft law on vaccination voted by the Roman legislature and its controversies

Arguing with provisions from its basic law - art. 34 al. 2 of the Romanian Constitution stipulating that "the state is obliged to take the necessary measures to ensure public hygiene and health" - and with the provisions of the UN Convention on the Rights of the Child adopted by the United Nations General Assembly on 20 November 1989 and ratified by the Romania Law no. 18/1990²², the Romanian

¹⁹ Case *N. W and Others v Sanofi Pasteur MSD SNC and Others*, Judgement of the Court on 21st of June 2017 in Case C-621/15, <http://curia.europa.eu/juris/celex.jsf?celex=62015CJ0621&lang1=ro&lang2=EN&type=TEXT&ancre=> (accessed 30.04.2018).

²⁰ Sarah Knapton, *European Court of Justice ruling could open floodgates for spurious vaccination claims*, article published in Telegraph UK on 22.06.2017, <https://www.telegraph.co.uk/science/2017/06/22/european-court-justice-ruling-could-open-floodgates-spurious/> (accessed 28.04.2018).

²¹ Facts: Mr. J.W. received a series of hepatitis B vaccine starting in December 1998, and ending in July 1999. Starting in August 1999 his health deteriorated, and in November 2000 he was diagnosed with multiple sclerosis (MS), which is an unpredictable, often disabling disease of the central nervous system that disrupts the flow of information within the brain, and between the brain and body. The cause of MS is still unknown – scientists believe the disease is triggered by as-yet-undefined environmental factor in a person who is genetically predisposed to respond. Mr. W.'s health continued to deteriorate, leaving him disabled. On October 30, 2011, Mr. W. died. His family sued Sanofi Pasteur, the manufacturer of the hepatitis B vaccine he received, claiming that the vaccine caused his MS. The law in France, mirroring the EU directive, required the plaintiffs to prove a defect in the product that caused his harm. French law required that plaintiff prove both the existence of a defect and that the defect caused the harm with "serious, specific and consistent presumptions." It also, apparently, made use of a number of legal presumptions. For a proper analysis see Dorit Rubinstein Reiss, *European court vaccine decision – a legal analysis*, article published on 25.06.2017 on Skeptical Raptor, <https://www.skepticalraptor.com/skepticalraptorblog.php/european-court-vaccine-decision-analysis/> (accessed 28.04.2018).

²² Published in the "Official Monitor of Romania", Part I, no. 109 of 28th September 1990 and republished in the "Official Monitor of Romania", part I, no. 314 of 13th June 2001.

legislator tried a courageous move through the legislative initiative on compulsory vaccination. Thus, by the explanation of the PL-x no. 399/2017²³ deposited with the Chamber of Deputies of Romania it is stated that this draft-law is inspired by the legislation of other European countries where the immunization rate exceeds 95%. Thus, in 11 European countries the immunization of children is compulsory, and the children are not accepted in the community if they do not have the complete vaccination scheme, Romania being far below the European average. For example, in Belgium, since 1967, the polio vaccine is mandatory. But when children are enrolled in the community, serums for pertussis, measles and mumps are also mandatory. In Slovenia, 9 vaccines are mandatory and 6 in Latvia. According to the draft-law, parents and legal representatives have the following responsibilities and obligations:

a) to ensure that the child is presented to the family doctor / health care provider to complete the age-appropriate vaccination scheme for mandatory vaccinations to ensure his/her right to health.

b) to present at the request of the County Vaccination Commission or of the Bucharest Municipality.

c) In the case of parents who are leaving the country and who leave children eligible for vaccination in the care of family members or other persons under the conditions stipulated by law, they are obliged to designate a person responsible for accompanying the child to the vaccination. In this regard, parents are advised to notify the family doctor in writing of the person's name within 15 days of receiving the information from the family doctor.

The draft-law was initiated due to the measles epidemic in 2016 - 2017 and to sharp rise in the number of children not vaccinated with the MMR (ROR in Romania) vaccine. MMR vaccine coverage (for measles, mumps and rubella, no) - the first dose for children aged 2 years was of 94.7 percent in 2011 and 95.1 percent in 2012. The number of measles cases in the 2016-2017 epidemic reached 4,070 in a very short time. Legislative intervention was necessary in the opinion of the Romanian Minister of Health due to the fact that, since the onset of the 2016 epidemic in Romania, 21 deaths were recorded in a first period in patients with unvaccinated measles, while in 2010-2015 there were only 4 deaths²⁴.

Almost 5% of parents refuse vaccination, and this led, according to Health Ministry officials, to the emergence of the measles epidemic. Most of the parents who refuse vaccination are not well informed, doctors say. On July 21st, 2017, the

²³ Explanation of the draft law on vaccination submitted to the Chamber of Deputies, <http://www.cdep.ro/proiecte/2017/300/90/9/em497.pdf> (accessed 28.04.2018).

²⁴ <https://stirileprotv.ro/stiri/actualitate/un-copil-de-un-an-si-jumatate-si-o-tanara-de-17-ani-au-murit-din-cauza-rujeolei-numarul-total-de-decese-a-ajuns-la-21.html> (accessed 28.04.2018).

number of measles diseases rose to 8,246 cases, of which 32 deaths, so it doubled in two months while the number of deaths increased dramatically²⁵.

The Romanian Health Ministry wants a mandatory vaccination law to force parents to immunize their children. The project says that "at birth, the parent has the right to refuse in writing the child's vaccination. Then, at the age of 3, when to be included in the community, the kindergarden cannot refuse the child because the child's right to education is guaranteed by the Constitution. But the parent is asked to submit the recovery schedule for the vaccination within two months. Those who do not submit will be charged with maltreatment of the minor and risk up to six years in prison. And the baby may be entrusted to the state and be vaccinated eventually".

The Draft Law on Vaccination stated, in the original version of art. 11, paragraph (4), let. n), among other attributions, the obligation of the County Vaccination Commissions and the Municipality of Bucharest to "refer to the competent institutions for the detection of the offense of maltreatment by the parents or legal representatives of the juvenile who reaches the age of 3 years and has not received the compulsory vaccines age-appropriate."

This particular provision, which has now been removed following a strong opposition from public opinion, has raised the question of the need to introduce into the draft law some clear criminalizing provisions to penalize parents or legal representatives who refuse to initiate or continue the compulsory vaccination scheme. As a matter of fact, by corroborating the provisions of the draft law (which does not provide criminalizing rules, but only an administrative sanction (fine), with those of the criminal law, it could be proved the committing of the offense of ill-treatment applied to the minor stipulated in art. 197 RCC. Thus, according to this text of incrimination the offense of ill treatments applied to underage persons consists in causing of serious jeopardy, through measures or treatments of any kind, of the physical, intellectual or moral development of an underage person, by parents or by any person under whose care the underage person and is punishable by no less than 3 and no more than 7 years of imprisonment and a ban on the exercise of certain rights. Obviously, in case of vaccination refusal in the context of an epidemic situation, with serious peril for the child's life, one can argue that the child's future physical development is in danger, so, an intervention through penal means is imperative. But is that so?

²⁵ Explanation of the draft law on vaccination submitted to the Chamber of Deputies, <http://www.cdep.ro/proiecte/2017/300/90/9/em497.pdf> (accessed 28.04.2018).

4. To vaccinate or not to vaccinate vs. to incriminate or not to incriminate. Moral and criminal boundaries

Everybody agrees on the complex features of the issue of vaccination while arguers should keep in mind its importance for the society and for public health. But in the same time regulating in the field of vaccination must be taken seriously for the fact that, if too low legal standards are set, dangers could result for the community. If legal standards imposed are too harsh, this could cause the violation of fundamental rights.

We cannot say for sure that compulsory vaccination results in improved vaccination rates because this result is highly dependant on country context, historical circumstance, cultural and social norms, as well as the practicalities of implementing and enforcing such a law. As Vanderslott and Roser stated, "certainly in Eastern Bloc countries when the vaccination law was compulsory, vaccination rates have been high but it is unclear whether to attribute this to the law or the behaviours and mechanisms of compliance under communist rule. Certain vaccinations have historically been compulsory such as smallpox, polio, and yellow fever. Here vaccination rates have also been high but it also encouraged organised opposition to vaccination and public discontent. This is a major concern for public health authorities that a relationship of trust, between governments and citizens is threatened (particularly for health where a rhetoric of self-responsibility, personalisation, and choice is encouraged)."²⁶ The authors underline the fact that there are countries with high vaccination rates without compulsory vaccination and governments do not want to disrupt public trust and self-responsibility by making vaccination compulsory, particularly if it is not seen as needed.²⁷ Alternative ways (such as education of the population, financial rewards etc.) are preferred. In recent years governments have acted in response to epidemics to modify their legislation in order to make vaccination compulsory (France, Italy, Germany, and Romania). But talking about modifying the legislation for this purpose is not the same with talking about criminalizing the refusal of vaccination, even if in limited circumstances.

4.1. Ethical boundaries

Bioethics is a new arena for jurists, a domain with so many incentive and novel features. Regulating in this area may be as difficult as it appears at a first glance, meaning that a set of principles is needed to ground the specific legislation. "These principles stressed the autonomy of the individual, not surprising given the

²⁶ Samantha Vanderslott, Max Roser, *Vaccination* (2018), published online at OurWorldInData.org, <https://ourworldindata.org/vaccination> (accessed 30.04.2018).

²⁷ Idem.

paternalistic and authoritarian manner that sometimes characterized modern medicine in the last century"²⁸.

Scholars were preoccupied to identify the basic and general directions of legal thinking proposing the following set: 1) producing benefits; 2) avoiding, preventing, and removing harms; 3) producing the maximal balance of benefits over harms and other costs (i.e., utility); 4) distributing benefits and burdens fairly (distributive justice) and ensuring public participation, including the participation of affected parties (procedural justice); 5) respecting autonomous choices and actions, including liberty of action; 6) protecting privacy and confidentiality; 7) keeping promises and commitments; 8) disclosing information as well as speaking honestly and truthfully (i.e., transparency); and 9) building and maintaining trust. Among these, three of them may be ranked as general principles of bioethics with an important moral core: benefitting others, preventing and removing harms, utility – while other three could lead to a conflict with them - justice, autonomy privacy – possibly limiting public health activities.²⁹

If we reduce our analysis to the most simple and obvious moral desideratum - do no harm to others - when applied to vaccination its implications are multiple: the vaccination should be of benefit to the subject being vaccinated; care should be taken to prevent any harm caused by vaccination; vaccination should be the best opportunity for successfully preventing disease as compared to the risk for harm; and if harm does result from the vaccination, the benefit of vaccination to the subject should at least compensate for the harm incurred.

In the same time the precautionary principle has been defined as being relevant to activities that concern public health with the aim to protect populations against reasonably foreseeable threats, even under conditions of uncertainty.³⁰

4.2. Penal boundaries

It is quite facile to use Criminal law to punish non-vaccinating individuals in the context of a death from preventable disease – the unvaccinated child, or someone infected as a result of his/her non-vaccination. The manslaughter

²⁸ Alvin Nelson El Amin, Michelle T. Parra, Robert Kim-Farley, Jonathan E. Fielding, Ethical Issues Concerning Vaccination Requirements, *Public Health Reviews*, Vol. 34: 14, No 1, p. 2, <https://doi.org/10.1007/BF03391666>.

<https://publichealthreviews.biomedcentral.com/track/pdf/10.1007/BF03391666>.

²⁹ James F. Childress, Ruth R. Faden, Ruth D. Gaare, Lawrence O. Gostin, Jeffrey Kahn, Nancy E. Kass, Anna C. Mastroianni, Jonathan D. Moreno, Phillip Nieburg, *Public Health Ethics: Mapping the Terrain*, *Journal of Law, Medicine, and Ethics* 2002; 30(2):170–178. <https://jhu.pure.elsevier.com/en/publications/public-health-ethics-mapping-the-terrain-3> (accessed 30.04.2018).

³⁰ L.O. Gostin, R. Bayer, A.L. Fairchild, *Ethical and legal challenges posed by severe acute respiratory syndrome: implications for the control of severe infectious disease threats*, *Journal of the American Medical Association* 2003, 290(24): 3229–3237, <https://www.ncbi.nlm.nih.gov/pubmed/14693876> (accessed 30.04.2018).

provisions are the proper tool. Different national legislations could request recklessness or just negligence to meet the required mental state for the manslaughter statute. Other legislations ban under criminal sanction the breach of parental duties and child abuse or neglect. But not vaccinating a child, particularly when there is no ongoing outburst, may not be perceived by a court as neglect, since it is very difficult to demonstrate the specific state of mind.³¹

Scholars showed that no parent has been prosecuted for the death of a non-vaccinated child from a vaccine preventable disease, but there were several cases where parents were prosecuted for failure to provide medical aid to a sick child. The question is if these cases could be extended to apply to a situation in which the child dies as a result of being unvaccinated. The arguments for admitting the extension are:

parents have a legal duty to provide medical aid to their children that can include providing the child with appropriate medication or taking the child to a doctor in appropriate circumstances. If a parent violates that duty and a child dies, a parent may be prosecuted under a manslaughter or homicide statute, depending on the circumstances.³²

But, against extension one can bring the issue of the *mens rea*: parents choosing not to vaccinate are acting like this for the child's benefit. If recklessness is required, it cannot be proved in this case that the parents were very negligent.

Not vaccinating is probably negligent: the risks of not vaccinating are substantially higher than the risks of vaccinating, and vaccinating is supported by an extensive medical consensus, but still negligence in this case seems wrong. Lot of parents who choose to vaccinate their children are educated and well informed on the issue of vaccination, so the *mens rea* required is missing.

Other sensitive issue is the religious argument. In some legislations religious exemptions exonerate a parent of child neglect for using faith healing; but as a counter-argument, one can emphasize that child does not get to choose the religion, and the parent should bear responsibility in this case.³³

In order to explain the social context in which a non-vaccinated person/child is involved, an author introduced the concept of "liminality". "The comparison of unvaccinated children to liminality is no doubt unintentional to their parents but exists nonetheless."³⁴ Liminality traditionally exists as a sociological theory of

³¹ Voices for vaccines, *Vaccines and the law. An Advocate s Toolkit*, 2014, <https://www.voicesforvaccines.org/content/uploads/2014/10/Vaccines-and-the-Law-Toolkit.pdf> (accessed 30.04.2018).

³² Dorit Rubinstein Reiss, *Rights of the Unvaccinated Child: Criminal Law*, 2014, <https://shotofprevention.com/2014/02/25/rights-of-the-unvaccinated-child-criminal-law/> (accessed 29.04.2018).

³³ Dorit Rubinstein Reiss, *Rights of the Unvaccinated Child: Criminal Law*, 2014, <https://shotofprevention.com/2014/02/25/rights-of-the-unvaccinated-child-criminal-law/> (accessed 29.04.2018).

³⁴ Cody Bondarchuk, *Redefining Mandatory Vaccination as Necessary to Life and the Refusal of Vaccination as Criminal Negligence Causing Death*, *Sociology Undergraduate Journal* Vol. 2 (2017), <https://journals.library.ualberta.ca/invoke/index.php/invoke/issue/view/1941> (accessed 29.04.2018).

being in-between life and death, and the same logic could be applied to an unvaccinated child., they simultaneously do and do not have the ability to be infected with the preventable disease, and the results cannot be determined until they either contract the disease or get the vaccine.

Finally, it is worth it to analyse the case-law of Romanian's neighbour, Hungary and the struggles of Hungarian doctrine to detangle the issue of criminalizing refusal of vaccination.

According to Section 208 (1) HCC³⁵ (*a.n. ex-section 195 (1)*) abuse of a minor is committed if the special subject of the crime, through the serious neglect of his obligation, endangers – in the present case – the physical development of the minor. Based on judicial sentencing, the commission of the crime may be established if the breach of duty endangers the physical development of the minor directly, therefore, general, abstract danger is not sufficient for factuality. The person who refuses to vaccinate the minor commits the abuse of a minor offense.

Doctrine has presented several cases – such as Kaposvár and Székesfehérvár – which have shown different views of the public prosecutors. In the first case the prosecutor stated that vaccination was to be enforced within the framework of administrative proceedings and not by the instruments of criminal law, the physical development of the minor must be in danger *de facto* and causal relations must be established between this danger and the perpetrator's intentional conduct to this purpose. Therefore, considering these facts, the act does not constitute a crime. In the second case the prosecutor argued that the parents endanger the health of their children, and through it, indirectly, their physical development as well if they consciously hinder the administration of the compulsory vaccinations dependant on age at the most appropriate time. Namely, if the children do not receive the vaccination at the indicated time, they are exposed to the danger of such preventable diseases which may lead to serious complications or may even end by death. A third controverted case was that of a mother who had failed to provide her children with one of the compulsory vaccinations was given a suspended sentence of six months' imprisonment by the County Court of Csongrád. Because one of her children has suffered side effects after vaccine inoculation, she decided not to vaccinate the others. Despite her reasons to reject vaccination, the court convicted her as shown.³⁶

³⁵ HCC available at <http://www.parliament.am/library/Qreakan/Hungary.pdf> (accessed 29.04.2018).

³⁶ Cases presented by Lilla David, *The evaluation of the refusal to submit to compulsory vaccination in Hungarian criminal law*, *Revista de Științe Juridice* (2013) nr. 2:117-123, pp.119-120, drept.ucv.ro/RSJ/images/articole/2007/RSJ2/013Lilla.pdf (accessed 29.04.2018).

5. Conclusions

The issue of compulsory vaccination is, as shown in the present article, very difficult to approach and even more difficult to regulate under a single branch of law. We tried to demonstrate that criminal law may not be the most effective solution to force parents to vaccinate their children. It should be *ultima ratio* on the national Governments agenda on public health policy.

Maybe some national legislators have managed to impose vaccination even if they did not use penal instruments, and maybe in the Communist Era Europe was immunized, but, in the same time, cases presented and ruled by courts in different countries have shown how easy it is to cross the barrier of public utility and commit an authority abuse, violating fundamental rights, both of the parent and of the child or of the person forced to accept inoculation.

The solution is in the hands of the State which can think-out an efficient public health policy based on education of the parents and of the public opinion about benefits of vaccines and on alternative measures, such as specific benefits, light non-criminal sanctions, suspending the allowance for children etc.

It is difficult for the states to find through the legislative solutions adopted, a middle path between respecting individual autonomy and the public interest, as it is equally difficult to implement a common global strategy on vaccination, cultural, historical, social and economic features of each country having an overwhelming importance in establishing a State internal attitude towards the issue of vaccination.

References

1. BBC News (2013), High Court orders two sisters must receive MMR vaccine, article published on 11.10.2013, <http://www.bbc.com/news/health-24493422>, (accessed 30.04.2018).
2. Bondarchuk, C. (2017). Redefining Mandatory Vaccination as Necessary to Life and the Refusal of Vaccination as Criminal Negligence Causing Death. *Sociology Undergraduate Journal* Vol. 2, <https://journals.library.ualberta.ca/invite/index.php/invite/issue/view/1941> (accessed 29.04.2018).
3. Brown, M. (2002). The Politics of Penal Excess an the Echo of Colonial Penalty. *Punishment and Society*, no. 4/2002.
4. European Court of Justice. Case *N. W and Others v Sanofi Pasteur MSD SNC and Others*. Judgement of the Court on 21st of June 2017 in Case C-621/15, <http://curia.europa.eu/juris/celex.jsf?celex=62015CJ0621&lang1=ro&lang2=EN&type=TXT&ancre=> (accessed 30.04.2018).
5. Caulfield, T., Knowles, L., Meslin, E.M. (2004). Law and Policy in the Era of Reproductive Genetics. *Journal of Medical Ethics*, vol. 30. <http://jme.bmj.com/>

content/30/4/414.full?sid=c32779f1-8a54-4b71-b944-a5771774cd9e (accessed 28.04.2018);

6. Childress, J.F., Faden, R.R., Gaare, R.D., Gostin, L.O., Kahn, J., Kass, Nancy E., Mastroianni, A.C., Moreno, J.D., Nieburg, P. (2002). Public Health Ethics: Mapping the Terrain, *Journal of Law, Medicine, and Ethics*; 30(2):170-178. <https://jhu.pure.elsevier.com/en/publications/public-health-ethics-mapping-the-terrain-3> (accessed 30.04.2018).

7. David, L. (2013). The evaluation of the refusal to submit to compulsory vaccination in Hungarian criminal law. *Revista de Științe Juridice* nr. 2:117-123, drept.ucv.ro/RSJ/images/articole/2007/RSJ2/013Lilla.pdf (accessed 29.04.2018).

8. Demicheli, V., Rivetti, A., Debalini M.G., Di Pietrantonj, C. (2012). Vaccines for measles, mumps and rubella in children. *Cochrane Database Syst. Rev.*, Feb 15; (2): CD004407. doi: 10.1002/14651858.CD004407.pub3, <https://www.ncbi.nlm.nih.gov/pubmed/22336803> (accessed 30.04.2018);

9. Destefano, F., Price, C.S., Weintraub, E.S. (2013). Increasing exposure to antibody-stimulating proteins and polysaccharides in vaccines is not associated with risk of autism. *J Pediatr.* Aug; 163(2):561-7. doi: 10.1016/j.jpeds.2013.02.001. Epub 2013 Mar 30, <https://www.ncbi.nlm.nih.gov/pubmed/23545349> (accessed 30.04.2018);

10. El Amin, A.N., Parra, M.T., Kim-Farley, R., Fielding, J.E. (2012). Ethical Issues Concerning Vaccination Requirements. *Public Health Reviews*, Vol. 34: 14, No 1, <https://doi.org/10.1007/BF03391666>. <https://publichealthreviews.biomedcentral.com/track/pdf/10.1007/BF03391666> (accessed 30.04.2018);

11. Elmgren, L., Lia, X., Wilson, C., Ball, R., Wang, J., Cichutek, K., Pflieger, M., Katoh, A., Cavalerif, M., Southern, J., Jivapaisarnpong, T., Minori, P., Griffiths, E., Sohn, Y., Wood, D. (2013). A global regulatory science agenda for vaccines. *Vaccine*, Volume 31, Supplement 2: B163-B175, https://ac.els-cdn.com/S0264410X12015939/1-s2.0-S0264410X12015939-main.pdf?_tid=c0f4909a-5e97-4154-8917-53f9429a08c8&acdnat=1525087224_fff7f9ca967c6a06f6c73412bc15ffc8 (accessed 28.04.2018).

12. Explanation of the draft law on vaccination submitted to the Chamber of Deputies, <http://www.cdep.ro/proiecte/2017/300/90/9/em497.pdf> (accessed 28.04.2018).

13. Gostin, L.O., Bayer, R., Fairchild, A.L. (2003). Ethical and legal challenges posed by severe acute respiratory syndrome: implications for the control of severe infectious disease threats. *Journal of the American Medical Association*, 290(24): 3229-3237, <https://www.ncbi.nlm.nih.gov/pubmed/14693876> (accessed 30.04.2018).

14. <http://www.parliament.am/library/Orekan/Hungary.pdf> (accessed 29.04.2018).

15. http://www.repubblica.it/salute/medicina/2015/03/01/news/autismo_i_giudici_assolvono_il_vaccino-108441541/?refresh_ce (accessed 30.04.2018).

16. <https://stirileprotv.ro/stiri/actualitate/un-copil-de-un-an-si-jumatate-si-o-tanara-de-17-ani-au-murit-din-cauza-rujeolei-numarul-total-de-decese-a-ajuns-la-21.html> (accessed 28.04.2018).
17. <https://www.skepticalraptor.com/skepticalraptorblog.php/italian-mmr-autism-decision-overtuned/> (accessed 30.04.2018),
18. Huidu, A. (2010). Reproducerea umană medical asistată. Etica incriminării versus etica biologică. Studiu de drept comparat, Editura Lumen, Iași;
19. IAC Saint Paul Minnesota USA, Vaccination for Infants and Children, Age 0-10 Years, <http://www.immunize.org/catg.d/p4019.pdf> (accessed 30.04.2018).
20. Knapton, S. (2017). European Court of Justice ruling could open floodgates for spurious vaccination claims, article published in *Telegraph UK* on 22.06.2017, <https://www.telegraph.co.uk/science/2017/06/22/european-court-justice-ruling-could-open-floodgates-spurious/> (accessed 28.04.2018).
21. Madsen, K.M., Hviid, A., Vestergaard, M., Schendel, D., Wohlfahrt, J., Thorsen, P., Olsen, J., Melbye, M. (2002). A population-based study of measles, mumps, and rubella vaccination and autism. *N Engl J Med.* Nov 7; 347(19):1477-82. PubMed PMID: 12421889, <https://www.nejm.org/doi/full/10.1056/NEJMoa021134> (accessed 30.04.2018);
22. Mrozek-Budzyn, D., Kieltyka, A., Majewska, R. (2010). Lack of association between measles-mumps-rubella vaccination and autism in children: a case-control study. *Pediatr Infect Dis J.* May; 29(5):397-400. doi: 10.1097/INF.0b013e3181c40a8a. PubMed PMID: 19952979, <https://www.ncbi.nlm.nih.gov/pubmed/19952979> (accessed 30.04.2018);
23. Pradel, J.(2002). Droit penal compare, 2eme edition, Dalloz, Paris;
24. Roberts, R. (2017), Vegan mother forced by High Court to vaccinate her children, article published in *Independent UK* on 6.04.2017, <https://www.independent.co.uk/news/uk/home-news/vegan-mother-vaccinate-children-high-court-toxin-free-kids-mmr-anti-vaxxer-a7670881.html>, (accessed 28.04.2018).
25. Rubinstein Reiss, D. (2017). European court vaccine decision - a legal analysis, article published on 25.06.2017 on *Skeptical Raptor*, <https://www.skepticalraptor.com/skepticalraptorblog.php/european-court-vaccine-decision-analysis/> (accessed 28.04.2018).
26. Rubinstein Reiss, D. (2016). Italian MMR Autism Decision Overtuned, article published on 20.12.2016 on *skepticalraptor.com*,
27. Rubinstein Reiss, D. (2014). Rights of the Unvaccinated Child: Criminal Law, 2014, published online <https://shotofprevention.com/2014/02/25/rights-of-the-unvaccinated-child-criminal-law/> (accessed 29.04.2018).
28. SAGE Evidence to recommendations framework, Table 3 BCG vaccination at birth vs. at 6 weeks, http://www.who.int/immunization/policy/position_papers/bcg_vaccination_birth_vs_6weeks.pdf?ua=1, (accessed 30.04.2018).

29. Stănilă, L. (2015). Principiul precauției și etica incriminării. O abordare bioetică in D. Popescu, S. Rădulețiu (eds.), *Conference Proceedings*, Vol. 4, Post-Doctoral Research within Social and Humanistic Sciences, Editura Alma Craiova, 288-302.

30. Stănilă, L. (2015). *Provocările bioeticii și răspunderea penală*, București, Editura Universul Juridic;

31. Vanderslott, S., Roser M. (2018). Vaccination. Published online at OurWorldInData.org, <https://ourworldindata.org/vaccination> (accessed 30.04.2018).

32. Voices for vaccines (2014). Vaccines and the law. An Advocate s Toolkit. <https://www.voicesforvaccines.org/content/uploads/2014/10/Vaccines-and-the-Law-Toolkit.pdf> (accessed 30.04.2018).

33. World Health Organization. Definion of vaccine. <http://www.who.int/topics/vaccines/en/> (accesed 28.04.2018);

34. World Health Organization. Immunization standards. http://www.who.int/immunization_standards/vaccine_quality/en/ (accesed 28.04.2018);

35. World Health Organization. Recommendations for all immunization programs, Table 1: Summary of WHO Position Papers - Recommendations for Routine Immunization. http://www.who.int/immunization/policy/Immunization_routine_table1.pdf?ua=1 (accesed 30.04.2018).

36. World Health Organization. Weekly epidemiological record, 23 February 2018. 93th Year, no. 8, 2018, 93, 73–96, <http://www.who.int/wer>, (accesed 28.04.2018).