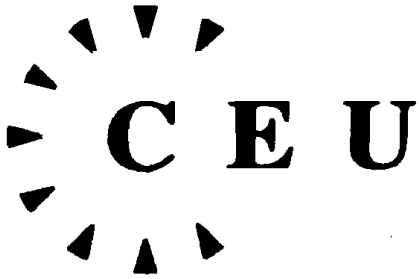

MANDATED PREVENTIVE HEALTH: WOULD HUNGARY'S VACCINATION LAWS SURVIVE STRASBOURG SCRUTINY?

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I. INTRODUCTION

The rights of choice, in this case, whether to choose or to reject vaccination, has a recent history dating to the civil rights movements of the 1970's. This thesis examines the longer historical context of this method of preventive health, and the legal parameters of this choice for Hungary as a new member of the European Union. Given its membership in the Council of Europe, the question is raised whether present-day vaccination laws protect or detract from rights of Hungarians as citizens of a modern Europe.

The historical success of mandatory vaccine programmes is widely recognized. They are considered to be among the most important public health interventions of the last century.[1] Credited with eradicating lethal diseases such as smallpox and wild-type polio, vaccines are generally believed to be the most effective means of eliminating communicable diseases and preventing epidemics.[2] Compulsory programmes are based on statutes which oblige individuals to comply with strategies designed to achieve high levels of immunization. Yet since this type of legislation was first introduced it has continually been the subject of widespread legal claims and heated debate. For some, the issue of whether the benefits requiring coercion outweigh the ethical problems associated with them is still a moot question.[3]

[1] Centers for Disease Control and Prevention, "Ten Great Public Health Achievements, 1900-1999: Impact of Vaccines Universally Recommended for Children," *Morbidity and Mortality Weekly Report* 24 (1999), 243; J. Ehreth, "The global value of vaccination," *Vaccine* 21 (2003), 596.
[2] G. Hodge and Lawrence O. Gostin, "School Vaccination Requirements: Historical, Social and Legal Perspectives," *Kentucky Law Journal* 90 (2002), 831-890; Susan L. Plotkin and Stanley A. Plotkin, "A Short History of Vaccination," in *Vaccines*, Stanley A. Plotkin and Walter A. Orenstein, ed. (Philadelphia: Saunders, 1999), 1-12.
[3] P. Bradley, "Should Childhood Immunisation be Compulsory?" *Journal of Medical Ethics* 25 (1999), 330-334.

In recent years, concerns over vaccine-related health risks have also reverberated in the international media. Along with anecdotal evidence, an increasing number of medical studies have raised concerns about the safety and effectiveness of vaccines. These doubts have led to reconsideration of the risk/benefit ratio and for demands for further testing. The vast majority of medical authorities and governmental bodies have dismissed these fears as being unfounded. But over the last few decades some communities have become more insistent on exercising their right to autonomous decision-making in matters of health. As a result, administrations are faced with polarized public views about the risks and benefits associated with vaccines.

In most Western countries compulsory vaccination was established long before the concept of informed consent. Such consent took root at a time when civil rights movements were growing. The Civil Rights Movement modified considerably the perception of the position of the citizen within a democracy and the rights of choice: such as to vaccinate or not to. While mandatory vaccination is recognized as state interference with fundamental rights, the legitimacy of such interference is a question which in a healthy democracy will remain open to discussion and to scrutiny.

Absent from the debates about mandatory vaccination legislation is the question of whether the legal foundations which may have existed at the time they were introduced remain legally sound today.

The aim of this thesis is to examine whether the legal basis of compulsory vaccination is defensible by considering it within a European rights-based framework.

The argument will be developed in three steps. First, a theoretical overview of the ethical questions relevant to mandatory vaccination will be offered. Against this background the importance of bodily self-determination, parental autonomy and the doctrine of informed consent will be discussed. In the second part, the arguable legal basis for state interference will be analyzed in light of provisions guaranteed under the European Convention on Human Rights and Fundamental Freedoms, which Hungary became a party to when it joined the Council of Europe in 1990. Hungary's vaccination policy will serve as the object of assessment. In the final part the justification for state involvement in decisions about health interventions will be evaluated; it will be concluded that mandatory vaccination legislation is ethically and legally tenuous, and recommendations for improving it will be offered.

II. RISK ASSESSMENT

The term of "mission creep" is used to describe a situation in which a mission, flush with recent success, is expanded beyond its original mandate into new areas beyond its competence. As an idiom it is very apt in suggesting how a project may acquire a life of its own and ultimately become difficult or impossible to manage. Its applicability to the rationale of immunization practices is evident, particularly in light of the ever greater number of vaccines added to the mandatory schedule. Initially, the purpose of vaccination was protection from exposure to contagious and life-threatening diseases, but vaccines have proliferated well beyond the frontier of their original function. Aggressive marketing of new vaccines, which, it is contended, will protect children from illnesses that range from influenza to cocaine addition, have increased public demand while not necessarily allaying public fears and anxieties.

One way of addressing and managing the risks posed by newly-introduced technologies is the invocation of what is called the "precautionary principle." This principle has received various formulations: It has been incorporated, for example, into the texts of several international treaties, including the Kyoto Protocol on Global Warming.[4]

One of the best formulations is that offered in January 1998 by a panel in the US, Canada and Europe and known as the "Wingspread Statement on the Precautionary Principle": When an activity raises threats of harm to human health or the environment, precautionary measures

[4]Rampton Sheldon and John Stauber, *Trust Us, We're Experts*, New York: Putnam, 2001, 23.

should be taken even if some cause-and-effect relationships are not fully established scientifically."[5]

Thus, scientific uncertainty cannot be allowed as a defence for inaction in the face of a potential threat. That this is necessary can be easily illustrated by a number of cases where harms caused by new technologies could not be demonstrated either at the time of their introduction or even for decades afterward. Perhaps the most notorious example is provided by the effect of chlorofluorocarbons like Freon on the earth's ozone layer. Scientific warnings about potential dangers were dismissed, based on well-reasoned, theoretical arguments, and CFC's were very widely used for decades until the incontrovertible evidence of a hole in the ozone was discovered.

With regard to vaccines, much evidence of harm can be likewise dismissed as merely anecdotal, and in the absence of the application of the precautionary principle, potentially highly dangerous vaccines may continue to be administered.

Such "anecdotal" evidence of harm is not far to seek. Since 1919, several hundred medical studies have linked neurological disorders such as myelitis, Guillain-Barré Syndrome, Reye's Syndrome and Encephalopathy with vaccination.[6] An exponential increase in autoimmune disease has led some researchers to investigate vaccination as a possible cause. Vaccination has also been pointed to in studies of the aetiology of multiple sclerosis, asthma, allergies, and

[5] Ibid, 24.

[6] Michael E. Horwin, "Ensuring Safe, Effective and Necessary Vaccines for Children," *California Western Law Review* (2001) 37, 33 (note 63).

Crohn's Disease.[7] Many of these links are thus far only correlations, but the correlations can be troubling. A dramatic rise in rates of autism (a 210% increase in California in the decade before 1998) has provoked many to look to vaccination as a factor for the increase.[8]

[7] Ibid.
[8] Ibid, 330 and notes 66-72.

III. PARENTAL AUTONOMY V. PUBLIC AUTHORITY

In all discussions of the merits and justification of compulsory versus voluntary immunization programmes, one purely empirical consideration has a preeminent role: the question of community protection. The success of a vaccine programme is linked with the number of individuals vaccinated; the benefit, however, is not just for the immunized, but for the community as a whole, since the immunization of a sufficient number in a community, so-called "herd immunity" (also known as "herd protection," "herd effect" and "community immunity"), will reduce the overall chance of infection.[9] If such coverage is high enough, the disease may even be considered eradicated. But low or insufficient coverage, it is said, may presage a return of outbreaks or even epidemics of particular illnesses. Accordingly, the nature of the legally mandated forms of persuasion used by a government will vary significantly, both in type and severity, depending on the level of coverage attained. Each of these forms of persuasion has its advantages but is also open to a number of objections.

These criticisms and objections raised against compulsory vaccination are usually based on perceived infringements of civil liberties and parental rights; those raised against various incentive programmes, however, depend more on empirical considerations. We will examine these first, before addressing the more involved issue of compulsory vaccination.

[9] Guilherme Gonçalves, "Herd Immunity: Recent uses in Vaccine Assessment," *Expert Review of Vaccines* 7 (10) (2008), 1493-4.

Perhaps the least controversial instrumentality that can be employed by a state to increase the numbers of those voluntarily seeking or consenting to immunization for their children is education. Widely diffused information and awareness-raising campaigns have been exclusively relied on by countries such as Finland, Germany, Sweden and The Netherlands, which have voluntary immunization programmes without any impairment to their maintenance of high levels of coverage and resultant herd immunity.[10]

In other countries, the dissemination of pro-vaccination information can be coupled with a more insistent approach by health care workers in giving immunization advice to parents. In Ireland, the UK and Italy, parents refusing immunization for their children may be required to sign consent refusal forms, or to attend a formal interview to give their reasons for refusing.[11] This denies parents the possibility of a passive, non-defended refusal but it could also discourage parents from contact with doctors.[12] Healthcare workers, in turn, may be pressured to vaccinate by government target-setting, as in the UK and Ireland, or by having their professional evaluation depend on immunization coverage.[13] More open to objection are various countries' incentive programmes for encouraging vaccination. Financial or material incentives can be seen to have a greater impact on poorer families; thus encouraged to immunize, lower-income families may take on an unfair share of risk by protecting better-off families from both vaccine-preventable illnesses and the risks of vaccination.[14] Financial incentives may also be offered to healthcare

[10] Torbjörn Tannsjö, *Coercive Care: The Ethics of Choice in Health and Medicine.* London: Routledge, 1999, 28.

[11] N. E. Moran et al., "From Compulsory to Voluntary Immunisation: Italy's National Vaccination Plan (2005–7) and the Ethical and Organisational Challenges facing Public Health Policy-makers across Europe," *Journal of Medical Ethics* 34 (2008), 671.

[12] Ibid.

[13] Ibid.

[14] Ibid, 167.

professionals to encourage them to vaccinate, which could be negatively construed as depending on said professionals' willingness to put financial gain before the best interests of their patients. Such a perception could erode public confidence in healthcare workers and their advice and result in a potential decline in immunization coverage.

From purely pragmatic criticism that can be levelled against the foregoing methods, we can turn to the more ethically contentious area of compulsory immunization. Such compulsion may be direct, in the form of fines or even imprisonment, or indirect, by refusing school registration to non-immunized children. Objections to compulsory immunization are usually couched in the language of rights and civil liberties; defences of such programmes may also be made by appealing to other sets of rights. Most frequently invoked in such discussions are: children's rights to healthcare; parents' rights to raise their children according to their own standards; and the right of the community to be protected against preventable diseases.

Which of these sets of rights should have precedence when they are perceived to be in conflict forms the substance of the ethical debate over compulsory vaccination. In the case of indirect compulsion through tying school enrolment to vaccination, a child's basic right to education is placed in conflict with the community's right to protection. Only if the risk to the community is clearly and directly threatened would this seem justifiable. Thus, the consideration adverted to at the outset, that of achieving a level of immunization coverage that permits herd immunity, will necessarily weigh heavily in the balance in such debates.

For its proponents, compulsory vaccination has the advantage of ensuring the protection of the community in a manner that distributes the risks and benefits of immunization equitably throughout the population.[15] It also by-passes parental decision-making, thereby forestalling the putative risk that a parent may not have the best interests of the child at heart.[16] For its opponents, however, such an infringement of parental rights is unconscionable. These rights are presumed to inhere in the relationship between parents and children for two main reasons: firstly, the parents' biological connection with the children may make them both the most directly interested in the welfare of the children and best suited to provide for it; secondly, the parent-child relationship may be considered to carry a unique social value and therefore to be inviolate and entitled to privacy protection. Action by the state that interferes with parental rights so construed would both weaken the socially valuable institution of the family, and destroy public trust in the state.[17]

Cases where parental rights are in conflict with the child's right to healthcare and end up before the European Court of Human Rights are not hard to find, as in the case of refusal of life-saving procedures such as blood transfusion. In such cases it will always seem at least reasonable to ignore parental wishes: whatever wrong parents would endure as a result cannot compare with the harm suffered by the death of a child.[18]

[15] Daniel A. Salmon, "Mandatory Immunization Laws and the Role of Medical, Religious and Philosophical Exemptions," *British Medical Journal* 378 (2007), 398.

[16] A. J. Dawson, "The Determination of Best Interest in Relation to Childhood Immunisation," *Bioethics* 19 (2005), 199-201.

[17] Marcel Verweij and Angus Dawson, "Ethical Principles for Collective Immunisation Programmes," *Vaccine* 22 (23-24) (2004), 3124.

[18] Daniel A Salmon, "Compulsory Vaccination and Conscientious or Philosophical Exemptions: Past, Present, and Future," *Lancet* 367 (2006), 440.

It is, of course, not necessary that immunization coverage always be one hundred percent. Therefore, there could be generous room for exemptions on religious or "philosophical" grounds. This would go against the principle of universality mentioned above, but it would be unlikely that objections would be made on that account.

IV. HUNGARIAN LAW AND PRACTICE

Aside from these empirical issues, are there other more general considerations relating to the social context of vaccination laws that would impeach their legitimacy? In the following section I will address this question by discussing the impact of Hungary's Socialist legacies on rights claims, political management of public interests and expectations.

VI. i. The Miry Ground of Transition Hungary

Lawrence Gostin offers some basic criteria indispensable to the success of any public health measure, but all too often overlooked: good governance, monitoring mechanisms, full disclosure and rights protection; These are some of the conditions without which instruments designed to promote health will likely fail.[19] When examining any government policy in Hungary, it is important to consider, *inter alia*, the criteria advocated by Gostin. Historic factors, political culture and norms are also key elements in evaluating the value of a policy.

Although Hungary has been a party to the Convention since 1991, many of its institutions, regrettably, preserve old Party conventions. As a result, social trust in public institutions is low.[20] The roots of Hungary's rigid enforcement of its vaccine regime go back to Socialism, according

[19] L. O. Gostin, "International Infectious Disease Law: Revision of the World Health Organization's International Health Regulations," *Journal of the American Medical Association* 291 (21) (2004), 2624-5.

[20] Elemér Hánkiss, "Games of Corruption: East-Central Europe, 1945-1999," in *Political Corruption in Transition: A Skeptic's Handbook*, ed. Stephen Kotkin and András Sajó, (Budapest: CEU Press, 2002).

to many health care practitioners.[21] Under the old establishment, the idea that individual rights must be subordinated to community rights was acceptable, and legally enforced. Two decades later, social support for individual rights still remains modest.

As Hungarian legal analyst Zoltán Fleck has observed, remnants of Socialist-era illiberal forces continue to serve as obstacles to necessary legal reforms, most conspicuously perhaps in the realm of the judiciary.[22] A recent study carried out by PEW, an American think tank, examined attitudes towards the transition period in Central and Eastern Europe. The results support Fleck's bleak assessment, revealing that, twenty years after the regime change, a mere 17% of Hungarians believe that democracy is working and the vast majority have no hope that the political arena can be either influenced or reformed.[23]

A key problem for rights recognition is the political elite's indifference to public opinion. While legal measures have been instituted over the years to allow Hungary to qualify for membership in international organizations or to quell criticism from EU institutions, these have not always led to appreciable changes.[24] A culture of entrenched subservience combined with deeply-rooted

[21] Among them Mihály Kökény, Head of the Hungarian Parliamentary Health Committee, expressed this opinion in an interview with Origo News. "Szúrni vagy Nem Szúrni?" [To Prick or Not?], Origo, 13 October, 2009.

[22] Zoltán Fleck, *Bíróság Mérlegen I-II* [Courts in the Balance], Budapest: Pallas Kiadó, 2008; In her analysis of transformations in human rights in Central Eastern Europe Catherine Dupré goes further, arguing that judicial reform, along with other prerequisites for democracy (including freedom to express dissent) were merely the "tip of the iceberg" and "[…] the breadth of human rights reforms was sometimes underestimated." Catherine Dupré, "After Reforms: Human Rights Protection in Post-Communist States," *European Human Rights Legal Review* (5) 2008, 622.

[23] "Public Opinion Two Decades after the fall of the Berlin Wall," Pew Global Attitudes Survey of 14 Nations, Fall 2009.

[24] Dupré maintains that the practice of mimicking Western human rights protection frameworks "seems to have been reinforced by a well-honed skill developed under communism, namely the ability to use the official rhetoric and to take part in the [human rights] discourse, while not necessarily adhering to the reforms' aims and, in some cases, not even taking any steps towards actual implementation of change" Catherine Dupré, "After Reforms: Human Rights

autocratic political structures are characteristic of all former Soviet Bloc countries. But serious deficiencies in personal rights of Hungarians continue to cast a shadow on administrative practices and some of the most important principles of the Convention have yet to be incorporated into practice.

VI. ii. Hungary's Vaccination Agenda

Hungary's vaccine uptake rate is among the highest in the world, with consistent coverage rates of nearly 100% from the 1980's up to the present.[25] While it is not the only country to have established sanctions for failing to comply with its vaccination protocols,[26] it may be distinguished by its militant-like enforcement mechanisms. These include threatening members of the medical community with revoking a license if they publicly doubt the necessity or question the safety of some vaccines.[27]

Despite these impressive figures, national and international epidemiologists have continued over the years to described Hungary's system as "ineffective in promoting good health," adding,

Protection in Post-Communist States, *European Human Rights Legal Review*," (5) 2008, 628; See also Pierre Kende, "L'optimisme Institutionnel des Elites Postcommunistes" in *Les Politiques du Mimetisme*, Y. Meny ed., Paris: L'harmattan, 1993.

[25] For WHO-UNICEF immunization coverage rates in Hungary, see Appendix A; for Hungary's current vaccine schedule, see Appendix B.

[26] Other countries with compulsory vaccination laws are Australia (6/8 states), Belgium (for polio), Canada (3/13 provinces), Czech Republic, France, Italy, Poland, Slovakia and USA; the degree of enforcement exercised and exception categories vary significantly. Source: Caleb Ward, "Compulsory Childhood Vaccination: A comparative analysis of vaccination programmes in OECD Countries," *Policy and Law* (2007), 49.

[27] Interview with Zoltán Leleszi, Nyitott Kapu legal consultant, November 13, 2009.

perhaps unnecessarily, that "[t]here is considerable disillusionment with the health services."[28] Among the key challenges identified are a "lack of rational decision-making in health care" and a "reluctance to define and rank priorities and evaluate outcomes […] vital for rational policy-making."[29] The notion of informed consent has yet to be accepted in practice. While Hungarian legislation guarantees the right to informed consent for all medical interventions, it is rarely respected. Although vaccination is mandatory, effectively eliminating choice, by law the patients still have the right to know what risks are involved in the procedure and what alternatives exist and should give their consent to any procedure. In Hungary this protocol is almost never applied in practice;[30] though this is by no means unique to Hungary.

In a culture of immunity, the effects of the marriage of political corruption and private "incentives" are predictable.[31] One of the notorious features of endemic corruption is an absence of trust in public institutions. Feelings of resentment and mistrust continue to linger in Hungary

[28] Eszter Ujhelyi et al., "Overview of the National Health Care System in Hungary," in *Country Report: Hungary*, EU Partnerships to Reduce HIV & Public Health Vulnerabilities Associated with Population Mobility, September 2007, 21-2.

[29] Ibid, 23.

[30] Stefánia Kapronczay, Head of Patient's Rights Program, Hungarian Civil Liberties Union, e-mail message to author, November 27, 2009.

[31] The Hungarian Ministry of Health concluded an agreement with the Glaxosmithkline in 2006. The pharmaceutical company possesses exclusive rights to supply the country with all of the state-recommended and mandated vaccines. The terms of the agreement have yet to be disclosed and the contract, which will come up for renewal in ten years, has not been published (Communication with Béla Gergely, legal advisor for the Állami Népegészségügyi és Tisztiorvosi Szolgálat (ÁNTSZ), the institution that enforces compliance with Hungary's vaccination laws. November 10, 2009) despite Hungarian legislation requiring ministries to make all public contracts available (Personal communication. Állami Számvevőszék [Hungarian Court of Auditors]. November 12, 2009). What is more, with the exception of government ministers, there exist no conflict of interest clauses requiring officials involved in policymaking decisions to disclose private affiliations which may exist with businesses involved in the bidding process (Interview with Zoltán Leleszi, Nyitott Kapu legal consultant, November 13, 2009). It is less surprising then to learn that the level of pharmaceutical spending in Hungary is disproportionately high (31.2% of the health budget as compared to an average of 17.1%). OECD data reveals that the ratio of pharmaceutical expenditures to total health care costs is greater, per capita, than any other OECD country (OECD, Health Data 2009: *How Does Hungary Compare?*).

and are fed regularly by media coverage of corruption scandals. What follows these exposés is nearly always a failed attempt to hold such persons accountable.

A recent and widely-publicized case involving Omninvest, Hungary's H1N1 virus vaccine supplier has proven particularly valuable in drawing attention to some of the concerns raised in this argument.[32] Omninvest is an offshore vaccine manufacturer that supplies flu vaccines to Hungary. The conditions of a fifteen-year contract made with the government were classified as "secret" by the Ministry (as were the ingredients of the vaccines and the owner of the company). Grave reservations about this non-disclosure, and about the safety and necessity of the flu vaccine in question, were raised by the medical community and the public following the story.[33] When the Hungarian Ombudsperson's Office intervened with an appeal for transparency the Ministry insisted on its right to keep the terms of the contract secret. It also refused to reveal the owner of the company, publishing online only a small section of the contract.

Despite the daunting challenges such an environment throws up to any concerted civic action, opposition to mandatory vaccination policy does exist to a limited degree, with several hundred cases heard before the Hungarian courts annually.[34]

[32] Júlia Gáti, "Hitviták az influenzáról: Tű a szénakazalban" [Controversy about the Flu: Needle in a Haystack] *HVG* 47 (21 November, 2009), 6-9.

[33] "Háziorvos: Rémhír, hogy Kapkodva Készült a H1N1-oltás," *HVG* (October 06, 2009).

[34] Interview with Gábor Ráfis Hajdú, Director of the Nyitott Kapu Közhasznú Alapítvány [Open Door Public Benefit Foundation], November 15, 2009. Nyitott Kapu, an organization comprising doctors, lawyers and parents of vaccine-injured children, has been lobbying parliament to modify its vaccination policy since 1999.

Having taken into consideration the practical realities of the Hungarian situation, let us examine the constitutionality and consonance with the provisions of the European Convention of the laws currently in place.

V. LEGITIMATE STATE INTERFERENCE UNDER THE EUROPEAN CONVENTION

Hungarian vaccination laws have been chosen for this case study for two reasons. On the one hand, its preventive health programme may be envied for the exemplary level of herd immunity it has achieved through austere enforcement mechanisms. But paradoxically it also may represent a model that is deficient in many respects from a rights perspective due to a confluence of factors, which include a lack of transparency, social trust in government institutions, anti-corruption mechanisms and independent monitoring, as well as inadequate compensation schemes. All of these factors detract from its legitimacy, which are already questionable on a pragmatic level, as will be argued in this section.

VI. i. Are Hungary's Vaccination Laws Constitutional?

The question of whether the provision of the Health Code which allows the state to use coercive measures in the case of vaccine refusal[35] is constitutional was addressed by the Hungarian Constitutional Court in 2007 (39/2007 (VI. 20) AB határozat).

The argument was based on art. 60 § (1) of the Hungarian Constitution, which guarantees freedom of thought, freedom of conscience and freedom of religion, and art. 67 § (1), which safeguards the right of children to receive the necessary protection and care from their family, the state and society that is "required for their physical, mental and moral development."

[35] Hungarian Health Code (1997. CLIV), Regulation 154, art. 58 § (4).

While the Court upheld the law as being constitutional, it raised a number of important issues relevant to the present argument. It highlighted, for instance, the importance of the role of informed consent in healthcare[36] (regardless of the lack of decision-making freedom that vaccination laws entail), and asserted the right of a parent opposing the procedure to appeal impending sanctions until her legal remedies are exhausted[37]. Notably, the Court recommended implementation of regulatory mechanisms which would ensure the safety of state-mandated vaccines.[38] Finally, it ordered the parliament to amend art. 58 § (4) of the Health Code which permitted the state to either compel vaccination or apply sanctions before an appeal process had reached its conclusion.[39]

References were also made to the right to bodily integrity and privacy (based on the right to dignity and self-determination), citing Constitutional Court decisions which had earlier established these rights.[40]

The 2007 ruling nonetheless affirmed Hungary's right to interfere with an individual's fundamental rights where its aim is to protect the health of the community.[41]

[36] 39/2007 (VI. 20) AB határozat, 4.1. (1) and 3.1.
[37] Ibid, 2.4.
[38] Ibid, 4.2.1.
[39] Ibid, 1.
[40] Ibid, 4.1.
[41] Ibid., 3.4.2.

Are there legitimate grounds for this type of coercive law? The question involves two inter-related issues. The state is allowed restrictions of rights justified for reasons of public policy, public security, or public health; it is for the ECtHR to determine whether the restrictions placed upon an individual are legitimate and proportionate in light of the objectives pursued. A parallel, but ultimately central matter, germane to the issue of compulsory vaccination, is the question of margin of appreciation.

VI. ii. Do these Laws Violate Rights under the European Convention?

Public health authorities in Europe have traditionally limited individual rights in cases where the health of the community was threatened. According to compulsory vaccination policies which fail to offer exemption possibilities, however, these same liberties are legally restricted on grounds that, under some circumstances, might be easily called into question. It is generally recognized that there are circumstances under which departing from neutral state functions are justified. But is such interference reasonable when a parent is compelled under threat of sanctions to vaccinate her child without her willing consent, when commensurate gains in community protection are not achieved? This is currently the case under Hungarian law, but under the European human rights framework there is some reason to believe that the rationale of public health authorities may not be sufficiently persuasive.

According to art. 8 (1) of the ECHR, a person's right to respect for his private life, home and correspondence is guaranteed. The case of forced vaccination would fall into this category, as the

ECtHR will "consider anything having to do with personal health… as part of private life."[42] Elsewhere, the Court has ruled that "…[o]ther aspects of privacy, such as health, may be just as 'intimate' [as sexual intimacy], albeit much more vital" and "[…] privacy is an aspect of the person's general well-being and not necessarily only an end in itself. The intensity of the State's permissible interference with the privacy of the individual and his or her family should therefore be seen as being in inverse relationship with the damage the interference is likely to cause to his or her mental and physical health."[43]

Hungary joined the Council of Europe immediately following the change of regime[44] and ratified the European Convention on Human Rights and Biomedicine (Oviedo Convention) on January 9, 2002.[45] While the Oviedo Convention is not directly applicable in Hungary, the Strasbourg Court has cited it on a number of occasions, referring to it as a "relevant international instrument" which makes its provisions legally binding through European case law.[46] The Court has also cited opinions and papers published by EU working groups (such as the European Group on Ethics in Science and New Technologies (EGE) and the Council of Europe's Steering Committee on Bioethics (CDBI)) in its judgements.[47]

[42] G. Cohen-Jonathan, "Respect for Private and Family Life" in *The European System of the Protection of Human Rights* Macdonald, Matscher, and Petzold, eds., (Dordrecht: Martinus Nijhoff, 1993), 405 (407).

[43] *Hatton and others v. United Kingdom* (App. 36022/97), Judgment of the Grand Chamber of 8 July 2003; (2003) 37 EHRR 611. § 10, as quoted in Clare Ovey and Robin C. A. White, *The European Convention on Human Rights* (Oxford: Oxford University Press, 2006), 297.

[44] November 6, 1990

[45] The Convention came into force on May 1, 2002.

[46] Judit Sándor, "Human Rights and Bioethics: Competitors or Allies? The Role of International Law in Shaping the Contours of a New Discipline," *Medicine and Law* 27 (2008), 17.

[47] Ibid, 23-4.

Hungary is bound by international law,[48] which under various instruments explicitly protects the right of an individual to control what happens to his body. For example, section 1 (1) of the Oviedo Convention provides that a signatory state "shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine," while section 1 (2) obliges a signatory state to "take in its internal law the necessary measures to give effect to the provisions of this Convention."

Art. 6 of the UN's Declaration of Bioethics and Human Rights also addresses the issue of consent, declaring that "any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information."

Additionally, art. 5 of the Oviedo Convention states that "[a] health intervention may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks […]."

Similarly, the right to "integrity of the person" is articulated in art. 3 of the Charter of Fundamental Rights, which declares that "[e]veryone has the right to respect for his or her physical and mental integrity" and that "[i]n the fields of medicine and biology, the following

[48] Art. 7 (1) of the Hungarian Constitution provides that "[t]he legal system of the Republic of Hungary accepts the generally recognized principles of international law, and shall harmonize the country's domestic laws with these obligations."

must be respected in particular: a) the free and informed consent of the person concerned, according to the procedures laid down by law […]."

The rights of informed consent, dignity and bodily autonomy raise the issue of the need to reconcile the protection of these rights with those arising from a state's obligation to protect the community from preventable threats to public health. More particularly, the question of the respective scope of the restrictions laid down in the second paragraph of art. 8, namely, that they must be lawful, motivated by one or more of the legitimate aims (in this instance, the protection of health or the protection of the rights and freedoms of others) and necessary in a democratic society (justified by a pressing social need and proportionate to the aim pursued).

In instances of an alleged violation of art. 8 involving a conflict considered ethically sensitive, the state will usually be granted a wider margin of appreciation.[49] Here, the Hungarian government might argue that privacy and bodily integrity are rights subject to limitations which are justified by the objective of public interest pursued through mandatory vaccination programmes, and that these are lawful, necessary and proportionate.

The litigant in such a case will have two advantages. Firstly, the objective, it may be argued, is not justified. The state would be hard-pressed to defend the mandated use of the Hepatitis B or Polio vaccine[50] in the case of young children, for instance. Secondly, given the degree of

[49] Judit Sándor, "Human Rights and Bioethics: Competitors or Allies? The Role of International Law in Shaping the Contours of a New Discipline," *Medicine and Law* 27 (2008), 27.
[50] In 2002 Polio was declared eradicated on the European Continent.

consensus that exists among experts (including the World Health Organization[51]) that accomplishing herd immunity does not require 100% uptake,[52] and that in any case high immunization coverage rates may be achieved by alternative means[53], the policy might likely be deemed disproportionate to its stated objective. Moreover, a widely accepted view in the public health field is the belief that, whenever feasible, persuasive approaches are better than coercive measures.[54]

On the one hand, the courts traditionally respond to challenges to public health policies with a "hands-off" approach. On the other, trust in public health authorities, the principle of respect for changing public expectations, and the doctrine of informed consent serve social needs of vital importance, and may be considered as such by the Strasbourg Court. The fate of a case often depends exclusively on how a particular issue is framed.

[51] The Hungarian Constitutional Court raised this issue in sections 3.2., 3.3. and 3.4.2 of the 2007 decision referred to earlier in this section. It is more than likely that the ECtHR would take this into special consideration; another domestic court case that might be taken into account is a 2009 judgment of the Hungarian Supreme Court (Bfv. II.25/2009/5. szám) which acquitted parents from criminal charges of endangering a minor. In its ruling the Court made several references to the Constitutional Court decision, notable the following: ["According to the decision of the Constitutional Court the mandatory vaccination policy and the establishment of its regulations amounts to a decisive restriction of the right to bodily integrity"]; ["The state may only interfere with fundamental rights when it is impossible for it to achieve legitimate objectives by any other means"]; and ["The legislature must limit itself to employing the least invasive methods for achieving its goal "] (Összefoglalóan: 879/B/1992. AB határozat, ABH 1996, 401).

[52] See Caleb Ward, "Compulsory Childhood Vaccination: A comparative analysis of vaccination programmes in OECD Countries," *Policy and Law* (2007), 48, and N. E. Moran et al., "From Compulsory to Voluntary Immunisation: Italy's National Vaccination Plan (2005–7) and the Ethical and Organisational Challenges facing Public Health Policy-makers across Europe," *Journal of Medical Ethics* 34 (2008), 669–674.

[53] See Marc Girard, "Vaccination and Auto-immunity: Reassessing Evidence," *Medical Veritas*, 2 (2005), 549-54, Weber, H. G. "High Immunization Rates – How can They be Achieved at All?" (Abstract of German paper). *Gesundheitswesen* 54 (10) (1992), 524.

[54] James Colgrove, "Immunity for the People: The Challenge of Achieving High Vaccine Coverage in American History," *Public Health Reports* 122 (2) (2007), 248.

Argued before the ECtHR, this dilemma offers an opportunity to assert the fact that parents that are denied the possibility of appealing for exemptions from national measures (applicable without distinction) are denied an important right. Such a violation is even less acceptable under circumstances where the state has gone beyond the necessary to achieve an intended aim. It is not immaterial for the purposes of evaluating the necessity and proportionality of a measure that many member states have taken alternative measures which have achieved the same objective while denying no parent the right to choose the preventive medical intervention of his choice.

There are substantial reasons for believing that the widespread trust in the professionalism of public health authorities in industrialized democracies may not always be warranted.[55] Authoritative assessments of public risk factors often differ considerably from what is presumed, with dismissal of medical evidence sometimes based entirely on potentially problematic public responses.[56] For instance, a significant share of public health data revealing the number of deaths that occurred due to vaccination in the UK was left unpublished (and hence unreported in medical journals or the media) until recently[57].

The principle of informed consent has deep historical roots in Western Europe. According to Anglo-American legal theories which can be traced back to the eighteenth century, any medical

[55] Lynn Payer, "Cultural Bias in Medical Science," in *Medicine and Culture: Varieties of Treatment in the United States, England, West Germany and France*, 23-34, New York: Henry Holt and Company, 1988.

[56] See, for instance, the work of Lynn Payer, who examined the degree to which non-medical factors influence medical decision-making in Western societies. She offers an example of public health officials responding to evidence suggesting that the value of a cholera vaccination was in effect negligible: "The fear of cholera is strongly felt by a large part of the population which still trusts vaccination practice as a control measure against the disease. We feel that our population, as well as that of other countries, would not agree to drop a protective measure, even if it has been scientifically demonstrated to be of little value," *Ibid*, 33.

[57] Sydney A. Halpern, *Lesser Harms: The Morality of Risk in Medical Research*, London: University of Chicago Press, 2004, 11.

intervention carried out without consent was considered battery.[58] Regulations stipulate that doctors must inform patients of the nature of the treatment they are advocating; they are also required to describe alternatives, report on the implicated risks of a medical treatment and allow for questions.[59] The practice of compulsory immunization schedules for young children, while long established, represents an exception to this principle.

Ongoing public debates about vaccines have a tendency to focus on the historical benefits of universally mandated inoculation programmes in contradistinction to the risk of adverse reactions that occur in a very small percentage of the population. However, these discussions as a rule fail to address the ethical and legal implications of more recent concerns about long-term and generational effects on the body's autoimmune system. An important number of independent studies indicate that dangers may indeed outweigh the benefits, or result in irreversible harm to present and future generations. This would naturally necessitate a revaluation of the risk/benefit ratio. The long-term hazards of vaccines are often the subject of fierce debate in medical circles, yet national health policies more often reflect the dominant opinion of the pharmaceutical industry than the concerns of anti-vaccinationist parents and the growing movement of civil society organizations opposed to the procedure.

The doctrine of informed consent allows for invasive procedures to take place legally. Since the late 1960's voluntary and informed consent is considered essential to any medical intervention. Regardless of whether the fears of anti-vaccinationists are legitimate, substantive issues

[58] Marc Stauch, Kay Wheat, and John Tingle, "Consent to Treatment," in *Sourcebook on Medical Law* (London: Cavendish Publishing Limited, 2002), 103.
[59] Peter Marks, "The Enigma of Consent," *Clinical Medicine* 1 (2) 2001, 118.

surrounding the debate raise important legal questions involving the compass and perimeters of consent. The importance of the precautionary principle and the need for greater research is particularly crucial when the state compels parents to have their children undergo immunization when they are unwilling to do so.

VI. CONCLUSION

All medicine possesses the potential to create undesirable side-effects. Vaccines are no exception, with a history of vaccine-related neurological and acute allergic reactions, permanent injury and death which date back to their inception; the risks associated with them were well-known at the time of their early development at the end of the nineteenth century.

However, some vaccines, once highly effective against a particular disease, have recently been shown to have lost their effectiveness over time. Since the active component in the vaccine is an organism, if that organism's genome changes due to evolution, then the vaccine may no longer work.[60] An example is the vaccine administered to prevent Tuberculosis, Bacillus Calmete-Guérin (BCG). According to a 2007 study helmed by the Institut Pasteur in France, BCG, a derivative of a TB pathogen in cattle, has mutated so much since its first use as a vaccine in the 1920s that it may no longer have any benefit.[61]

Availability of empirical evidence from certifiably independent experts should be a component of any programme that entails rights infringements and involves known and conceivable risks.

It is worth examining in more detail the example of one state which has moved away from a compulsory model for vaccination programmes, thereby avoiding controversies that will become

[60] Roland Brosch, "Genome Plasticity of BCG and impact on vaccine efficacy, Proceedings of the National Academy of Sciences of the United States of America," 104 (13) (2007): 5596-7.

[61] Ibid.

an increasingly common feature of the political landscape of states that do not revise immunization policies.

In Italy, before the introduction of the National Vaccination Plan of 2005-2007 (NVP), there existed both direct and indirect kinds of compulsion for childhood vaccination.[62] Direct compulsion took the form of fines; indirect compulsion was effected by tying school and nursery enrolment to possession of immunization.[63] Since coverage rates were high for compulsory immunizations and the incidence of the disease very low and with the aim of removing what was considered misleading distinction between recommended and compulsory immunizations, the government's National Vaccination Plan was passed in 2005. This gave the regions of Italy the responsibility for preventive health programmes and allowed them to suspend sanction connected with compulsory vaccinations if they have achieved specified minimum levels of coverage for each disease and can effectively monitor these coverage rates, outbreaks of disease and adverse effects caused by vaccines. Under these conditions, all vaccinations would become recommended or voluntary. Thus far, two Italian regions have met the criteria specified in the NVP, but it remains too early to gauge results.

The NVP programme is informed by an attitude which favours the dissemination of information and stresses participation and informed consent on the part of parents, an approach which is

[62] N. E. Moran et al., "From Compulsory to Voluntary Immunisation: Italy's National Vaccination Plan (2005–7) and the Ethical and Organisational Challenges facing Public Health Policy-makers across Europe," *Journal of Medical Ethics* 34 (2008), 668.
[63] Ibid.

generally recommended and believed to be the most effective by some.[64] This entails a move away from a coercive, confrontational, "paternalistic" model of state involvement to a co-operative one which empowers citizens rather than alienates them. It is hoped that this could prove a model for Hungary or other EU states that are looking to replace public health policies that are outdated, and perhaps in some cases, clash with Convention rights.

Decisions about the risks and benefits of different types of vaccines and mass immunization policies will require complex ethical and scientific problems to be evaluated. These are issues for answerable administrative bodies to determine rather than the judiciary. Still, public authorities are not used to opening up policy to various stakeholders. Parents are assumed to have the best interests of their children in mind when weighing the risks and benefits of a medical procedure as controversial as vaccination. The extent to which they will be prepared to further accept state intervention in this area, however, is a matter that may ultimately be decided before the courts.

The foundations of modern constitutionalism are built piecemeal through even-handed and reliable interpretations of rights by the judiciary. Nonetheless, strategic litigation in this area may encourage the courts to challenge current state health paradigms about disease control. Litigation may offer them the opportunity to address many of the rights violations that might otherwise remain invisible and unheard.

[64] C. Feudtner and E. K. Marcuse, "Ethics and Immunization Policy: Promoting Dialogue to Sustain Consensus," *Pediatrics* 107 (5) (2001), 1160-2.

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European Convention on Human Rights (1950)

Case Law

Hungarian Constitutional Court Decision 39/2007 (VI.20) AB
Hungarian Supreme Court Decision Bfv. II.25/2009/5. szám

Appendix A

WHO-UNICEF estimates of immunization coverage 1980-2008:

The Republic of Hungary

	2008	2007	2006	2005	2004	2003	2002	2001	2000	1999	1998	1997	1996	1995	1994	1993	1992	1991	1990	1989	1988	1987	1986	1985	1984	1983	1982	1981	1980
BCG *(Baccille Calmette Guérin vaccine)*	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99
DTP1 *(First dose of diphtheria toxoid, tetanus toxoid and pertussis vaccine)*	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99
DTP3 *(Third dose of diphtheria toxoid, tetanus toxoid and pertussis vaccine)*	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99
HepB3 *(Third dose of hepatitis B vaccine)*																													
Hib3 *(Third dose of Haemophilus influenzae type B vaccine)*	99	99	99	99	99	99	99	99	99	99																			
MCV *(Measles-containing vaccine)*	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99
Pol3 *(Third dose of polio vaccine)*	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	98	99	99	99	99	99	99	98	98	99	98	98

* indicates coverage was reported over 99.5%

Source: WHO vaccine-preventable diseases: monitoring system 2009 global summary (Last update: August 2009)

Appendix B

Hungarian Childhood Vaccination Schedule

	DTaP	IPV	Hib	PCV71	MMR	HepB	dT	BCG
At birth						Yes2		Yes
2 months	Yes3	Yes3	Yes3	Yes				
3 months	Yes3	Yes3	Yes3					
4 months	Yes3	Yes3	Yes3	Yes				
15 months				Yes	Yes			
18 months	Yes3	Yes3	Yes3					
6 years	Yes4	Yes4						
11 years					Yes		Yes	
14 years						Yes		

1 HepB vaccine is given at this stage to infants of HbsAg positive mothers and to mothers with unknown HbsAg status. Administered in 3 doses, starting within 12 hours post-partum (in case of HbsAg positive mother simultaneously with HB immunoglobulin), second dose 1 month later and third dose 6 months after first dose.

2 DTaP, IPV and Hib are given as the pentavalent combination vaccine.

3 DTaP and IPV are given as a combined vaccine.

Abbreviations:			
D	Diphtheria vaccine (normal dose)*	IPV	Inactivated polio vaccine
d	Low dose diphtheria vaccine (booster dose)*	t	Low dose tetanus vaccine (booster dose)*
T	Tetanus vaccine (normal dose)*	aP	Acellular pertussis vaccine (normal dose)*
MMR	Measles, Mumps and Rubella vaccine	IPV	Inactivated polio vaccine
HepB	Hepatitis B vaccine	PCV7	Pneumococcal heptavalent conjugate vaccine
BCG	Bacillus Calmette-Guérin vaccine	Hib	Haemophilus influenzae type b vaccine
		Hib	Haemophilus influenzae type b vaccine

Source: European Surveillance Community Network for Vaccine Preventable Infectious Disease (March 2009)