BIOTELL - Teaching European Law and Life sciences

CASEBOOK

Jean Monnet EUROPEAN CENTRE UNIVERSITY OF TRENTO

With the support of the Erasmus+ Programme of the European Union

BioDiritto

BIOTELL - Biolaw: Teaching European Law and Life Sciences (2017 - 2020) is a Jean Monnet module held at the Faculty of Law of the University of Trento and coordinated by Carlo Casonato and Simone Penasa.
Cover credits: Photo by Jessica Lee on Unsplash.

Jean Monnet EUROPEAN CENTRE UNIVERSITY OF TRENTO
With the support of the Erasmus+ Programme of the European Union
BioDiritto

BIOTELL - Teaching European Law and Life sciences

CASEBOOK

This Casebook is one of the final deliverables of the Jean Monnet module BIOTELL - TEACHING EUROPEAN LAW AND LIFE SCIENCES. It collects relevant materials on some of the topics addressed during the course, organized in the framework of the JM module, by the Faculty of law of the University of Trento. For each topic, experts involved in the activities of the project, offer a brief introduction and a selection of legislative and jurisprudential materials, as well as some fundamental bibliographical suggestions for in-depth study of the most crucial issues.

Table of contents

Jean Monnet EUROPEAN CENTRE UNIVERSITY OF TRENTO

With the support of the Erasmus+ Programme of the European Union

BioDiritto

BioLaw and EU sources of law

Elisabetta Pulice

I. Introduction

In this section we will provide a short overview of the sources of law directly or indirectly concerning principles of biolaw – understood as the set of legal rules regulating life sciences and new technology – within the EU legal system. This general overview is also intended to give some general remarks to contextualise the cutting-edge topics analysed in this case-book, which, by their very nature, are often ever-changing and multidimensional.

Under the principle of conferral, the European Union acts only within the limits of the competences conferred upon it by the Treaties. Within the division of competences between the EU and the EU Member States, as clarified by the Treaty of Lisbon, the EU is not able to legislate and adopt binding acts in the field of health (no exclusive competence). According to article 6 TFEU the EU has instead a supporting competence in the protection and improvement of human health. Accordingly, the EU can "support, coordinate or supplement the actions of the Member States".

In the area of "shared safety concerns in public health matters, limited to the aspects defined in the TFEU", as well as in the field of "research, technological development, space", the EU shares competences with the Member States (art. 4 TFEU), meaning that both the EU and EU Member States are able to legislate and adopt legally binding acts. The latter exercise their own competence where the EU does not exercise (or has decided not to exercise) its own competence.

Starting from this formal division of competences, the actions of the EU in the field of health are growing and expanding also beyond them, on the basis of both negative integration and cooperation between the Member States.

As a matter of fact, the EU framework for biolaw issues is primarily linked to the basic features of the EU integration process – starting from the ongoing pivotal role of the internal market toward an "ever closer Union" (Art. 1, TEU), in which, among other things, "fundamental rights form an integral part of the general principles of law the observance of which [the Court of Justice of the European Union] ensures" (see, inter alia, Case C-112/00 Schmidberger [2003], par. 71; Case C-36/02 Omega [2004], par 33, and article 6 TEU) – as well as to the scope and development of European Union health law and policy. From a general perspective, fundamental rights are the values on which both the Union and the Member States are founded (art 2 , 7 and 49 TEU), and, within the scope of the Charter of Fundamental Rights of the European Union (which, however, shall not extend the competences of the Union), they shall be respected by institutions and bodies of the Union and by the Member States (art. 6 TEU and art. 51 CFREU) .

Moreover, on the one hand, health issues have been brought and addressed by the CJEU under the market freedoms. On the other hand, provisions concerning EU actions on healthcare have been created and secondary legislation regulating related issues has been adopted.

To outline the basic elements of the legal framework for EU biolaw, the following sources of law should thus be considered.

Firstly, the Treaties as to the mentioned competences and the protection of fundamental rights.

The general legal basis of shared competences in the filed of health is embedded in article 168 TFEU, which introduced further types of measures as compared to the previous version (Article 152 TEC). While stressing the subsidiarity principle regarding to healthcare systems, the provision provides for EU competence to adopt measures concerning "monitoring, early warning of and combating serious cross-border threats to health" (§1) and setting "high standards of quality and safety for medicinal products and devices for medical use" (§4, letter c). Among the measures to be adopted in order to contribute to meet common safety concerns, those setting "high standards of quality and safety of organs and substances of human origin, blood and blood derivatives" (§4, letter a) also play an important role. Moreover, article 168 adds measures "which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States" (§5). Cooperation between Member States in these fields is encouraged by the EU, in particular "to improve the complementarity of their health services in cross-border areas" (§2). The principle according to which "a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities" has been strengthened and fostered, at both the EU and the national level, by collaborative and practical approaches such as Health in all Policies (HiAP) Health Impact Assessments (HIAs), which also contribute to introduce healthcare-related issues into other EU policy areas.

The Charter of Fundamental Rights of the European, which has the same legal value as the Treaties, includes several crucial provisions concerning biolaw: e.g. human dignity (art.1); right to life (art. 2); the right to physical and mental integrity; informed consent, the prohibition of eugenic practices and of the reproductive cloning of human beings (art. 3); the right to respect for private and family life (art. 7); the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices (art. 35).

Secondary legislation and, in certain given fields, the approximation process of provisions laid down by law, regulation or administrative action in Member States (Art. 114 TFUE) should also be mentioned, together with EU specific health policies and actions, such as those related to safety at work. Besides articles 168 TFEU (protection of public health) and 114 TFEU (approximation of laws), the EU can adopt legislation concerning health also under Article 153 TFEU (social policy).

From a general perspective, while EU Member States hold primary responsibility for organising and delivering health services and medical care (art. 168, §7 TFEU), the EU complements national health policies by supporting and funding common goals, shared challenges and health projects across the EU, as well as by formulating EU-wide legislations and standards for health products and services and fostering international cooperation. The EU actions in fields connected to public health concern therefore a variety of issues and aims related to biolaw, such as improving health systems (e.g. cross-border care, the creation of virtual networks involving healthcare providers, health technology and health systems performance assessment, the promotion of digital health and care, as well as of high levels of education, trainings, skills and adequate flexibility of health workforce); promoting good health by addressing topics such as social determinants of health, tobacco, alcohol, nutrition and physical activity; imposing and monitoring EU legal requirements on safety and quality for medical devices, substances of human origin (and namely blood, tissues, cells and organs), pharmaceuticals, endocrine disruptors, and biocidal products. A further field which plays an

important role within the EU's public health action is disease prevention and response, which includes sensitive topic such as vaccination, antimicrobial resistance, cancer, responsible food labelling, crisis preparedness and response to fight cross-border threats to health. Due to the COVID-19 pandemic the EU is adopting specific additional measures and actions to reinforce preparedness and response across Europe, aiming at helping to limit the spread of the infection, saving lives and strengthening the internal market's resilience [https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1986].

The functions performed by two agencies in supporting and assessing health issues are also worth mentioning, and namely the European Medicines Agency (EMA), entrusted with the scientific assessment of quality, safety and efficiency of all EU medicines, and the European Centre for Disease Prevention and Control (ECDC), entrusted with the assessment and monitoring of emerging disease threats in order to coordinate responses across the EU Member States.

The CJEU's case-law plays a crucial role in developing principles indirectly concerning EU biolaw. This is primarily related to the oldest core pillar of EU: the internal market.

The principles regulating the EU internal market, such as the free movement of the factors of production, free competition, and the mechanism of mutual recognition (following the Cassis de Dijon case law) may indirectly affect healthcare.

Just to give a few examples, free movement of services impacts healthcare provisions across borders. With reference to medical service the CJEU has held that "the special nature of certain services does not remove them from the ambit of the fundamental principle of freedom of movement" (Kohll, C-158/96, §20). Regarding national social security systems, the Court has also stressed that the provisions on the freedom to provide services "prohibit the Member States from introducing or maintaining unjustified restrictions on the exercise of that freedom in the healthcare sector" (Yvonne Watts, C-372/04, § 92). In relation to waiting lists the Court has underlined the role of an "objective medical assessment of the patient's medical condition, the history and probable course of his illness, the degree of pain he is in and/or the nature of his disability" to understand if the delay arising from waiting lists appears to exceed an acceptable time (Ibid, §68). Even a sensitive an controversial issue such as abortion has been addressed under the principles of the internal market, and namely the freedom of services: "medical termination of pregnancy, performed in accordance with the law of the State in which it is carried out, constitutes a service within the meaning of […]the Treaty" (Case C-159/90, Grogan, 1991, §16). Free movement of persons impacts important sectors, such as cross-border healthcare and social security. Also health workforce mobility is affected by market principles, especially freedom of establishment and freedom to provide services. Mutual recognition of medical qualifications and the following adoption of specific EU Directives for healthcare professionals concerning professional qualifications show the role and interactions between market principles, case-law and EU regulatory instruments. Patients' rights Directive and Tobacco Directives are other cases in point. With reference to mobility of professionals, the CJEU has also addressed the issue of the role of professional rules (including professional ethics) in decisions concerning both the need for their respect and their possible role in hindering free movement of professionals, also with reference to the disciplinary responsibility (in relation to healthcare professionals see for instance Case C-475/11, Konstantinides). Pharmaceuticals, medical devises, tobacco are examples of healthcare goods or good having an impact on human health, which are addressed also by freedom of goods and subjected to the related rules besides the abovementioned EU actions in these fields.

Moreover, concerns about the protection of health can justify prohibitions or restrictions on market freedoms. Consequently, CJEU case law may also impact national rules protecting such "grounds" (Article 36 TFEU) or "legitimate aims" (following the Cassis de Dijon case law), though the application of a quite strict proportionality test.
As far as the case-studies are concerned, Case C-333/14 regarding the interpretation of Regulation (EU) No 1308/2013 establishing a common organisation of the markets in agricultural products and of Articles 34 TFEU and 36 TFEU with reference to the validity of the Scottish legislation on the imposition of a minimum price per unit of alcohol ('MPU') with respect to the retail selling of alcoholic drinks in Scotland is a case in point. Further CJEU decisions show how biolaw issues can be dealt with starting from EU legislation regulating other topics not directly linked to them. In Case C-621/15, for instance, issues concerning vaccination are addressed by interpreting Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products. In Case C-179-16, issues related to the off-label use of medicinal products, the existence of a relationship of substitutability, as well as the role of the competition authority are addressed through article 101 of the TFEU prohibiting measures aimed at the prevention, restriction or distortion of competition within the internal market. Case C-528/13 addresses the issue of discrimination based on sexual orientation through the interpretation of point 2.1 of Annex III to Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC concerning certain technical requirements for blood and blood components. In Case C-528/16 the CJEU deals with the issue whether or not mutagenesis are, in principle, considered to result in genetic modification by interpreting some provisions of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms.

II. Selected materials

Relevant legislation and other documents

Patients' rights in cross-border healthcare

Directive 2011/24/EU on patients' rights in cross-border healthcare

Pharmaceuticals and medical devices (pharmacovigilance, falsified medicines, clinical trials)

REGULATION (EC) No 141/2000 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 1999 on orphan medicinal products

DIRECTIVE 2001/20/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use

DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to medicinal products for human use

REGULATION (EC) No 726/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

REGULATION (EC) No 1901/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004

REGULATION (EC) No 1394/2007 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004

REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

Detailed Commission guidelines on good manufacturing practice for investigational medicinal products for human use, pursuant to the second subparagraph of Article 63(1) of Regulation (EU) No 536/2014

Commission Implementing Regulation (EU) 2017/556 of 24 March 2017 on the detailed arrangements for the good clinical practice inspection procedures pursuant to Regulation (EU) No 536/2014 of the European Parliament and of the Council

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

Commission Directive (EU) 2017/1572 of 15 September 2017 supplementing Directive 2001/83/EC of the European Parliament and of the Council as regards the principles and guidelines of good manufacturing practice for medicinal products for human use

Commission Delegated Regulation (EU) 2017/1569 of 23 May 2017 supplementing Regulation (EU) No 536/2014 of the European Parliament and of the Council by specifying principles of and guidelines for good manufacturing practice for investigational medicinal products for human use and arrangements for inspections

Tobacco

Council Directive 2011/64/EU of 21 June 2011 on the structure and rates of excise duty applied to manufactured tobacco

DIRECTIVE 2014/40/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC

Organs, blood, tissues and cells.

Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC

Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

Guidelines: Coronavirus disease 2019 (COVID-19) and supply of substances of human origin in the EU/EEA -

Serious cross border health threats

DECISION No 1082/2013/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC

Selected bibliography

Alemanno A., 'Balancing free movement and public health: The case of minimum unit pricing of alcohol in *Scotch Whisky*' (2016) 53 *Common Market Law Review*, 4, pp. 1037–106

Guy M., Sauter W., The History and Scope of EU Health Law and Policy, in TILEC Discussion Paper No. 2016-002

Hennette-Vauchez S., L'union européenne: drôle d'endroit pour une rencontre entre droit et biomédecine, in M. Doat and P. Charlot (eds.), Détours juridiques : le praticien, le théoricien et le rêveur, Bruylant Edition, 2012, 341-380

OECD (2020), Health at a Glance: Europe 2020: State of Health in the EU Cycle, OECD Publishing, Paris

Penasa S, Biodiritto e Unione Europea: primi spunti di riflessione, in BioLaw Journal-Rivista di BioDiritto, 3, 2018

Ragone G., La disciplina degli OGM tra Unione Europea e Stati nazionali: a chi spetta il diritto all'ultima parola su questioni scientifiche controverse?, in BioLaw Journal-Rivista di BioDiritto, 1, 2015

Smillie L. R, Eccleston-Turner M. R, Cooper S. L; C-621/15 - *W And Others v Sanofi Pasteur*: An Example of Judicial Distortion and Indifference to Science, *Medical Law Review*, Advanced articles, 8 November 2017

Further useful links

European Commission - EU health policy and actions

European Commission's Directorate for Health and Food Safety (DG SANTE)

European Centre for Disease Prevention & Control (ECDC)

European Medicines Agency (EMA)

EU CCP Database - COVID-19 convalescent plasma collection and transfusion in the EU

Summaries of EU legislation on health

Medical research and clinical trials

Carlo Casonato

I. Introduction

Respect for fundamental rights has not always been a priority for clinical research. Unfortunately, the reference does not only go to the Nazi experience, to Auschwitz, Dachau, and Birkenau, where aberrant and inhuman experiments on transplant, infections, sterilization and fertility, resistance to extreme cold or toxic agents, depressurization, and so on were carried out. Even in Tuskegee (Alabama), until the early 1970s, some U.S. doctors working for the Public Health Service proceeded with research on syphilis, violating the most basic ethical and legal principles of informed consent and non maleficence.

The first signs of the law of clinical research, so, were formed by reaction to these infamous experiments: among the best known, the Nuremberg Code (1947) and the Belmont report (1979). In the time between the two documents, in 1964, the Helsinki Declaration was approved by the World Health Organization: a declaration that contains the main professional standards for clinical trials and all research activities. This way, resembling Beauchamp and Childress principialist approach, informed consent, protection for participants' health, a risks-benefit analysis, methodological robustness and a review by independent Institutional Review Boards (IRBs) or Ethics Committee piled up overtime, becoming general conditions for conducting any kind of clinical research.

i) The first element relates to the principle of informed consent: the need for the persons to be accurately informed about the essential elements of the study proposed, and to be able to express their genuine will, not being in any way forced or deceived in the decision whether or not to participate in the research. The participants should be provided with all information necessary to make a free and informed choice, including data about the nature, duration and purpose of the protocol, the method that will be used, and the foreseeable effects or hazards on health and well-being. In particular, the so-called therapeutic misconception must be avoided, clarifying that the primary objective of a clinical trial is not the direct benefit of the individual patients, but the collection of data necessary for scientific knowledge and future treatments.

Informed consent, particularly in the present period of Covid 19 pandemic, has been criticized. A first criticism revolves around the presumptive moral obligation to give it. According to Harris, for instance,

> «We all benefit from living in a society, and, indeed, in a world in which serious scientific research is carried out and which utilises the benefits of past research. It is both of benefit to patients and research subjects and in their interests to be in a society which pursues and actively accepts the benefits of research and where research and its fruits are given a high priority. We all also benefit from the knowledge that research is ongoing into diseases or conditions from which we do not currently suffer but to which we may succumb. It makes us feel more secure and gives us hope for the future, for ourselves and our descendants, and for others for whom we care.»

Informed consent, on these grounds, should not be a right but instead a (moral) duty. The weak side of the proposed theory, however, is that the principle of solidarity cannot be applied one-way. If participants are asked to always participate in clinical research for the benefit of the society, we must be sure that the research purpose is the real welfare of the community, and not the commercial interests of pharmaceutical companies, for example. However, a series of cases, from Sofosbuvir to Avastin-Lucentis, from Gleevec to Fentanyl, seems proving the opposite.

Another issue related to the informed consent principle is linked to clinical research done with data and samples collected in biobanks. Here, an as large as possible data sharing is needed in order to reach robust and reliable results; and the Covid 19 crisis is giving even more importance to the issue. A relaxation of informed consent, in this context, seems reasonable, provided that efficient measures to protect individual privacy are implemented, and that the research heads to a real benefit for the whole population and not to the profit of a few.

ii) The second general rule already provided by the Nuremberg Code and later refined by other documents refers to the protection of mental and physical health of participants. Accordingly, the safety and well-being of the people involved in the trial take always precedence over the interests of science and society. Following this principle, the trial should be conducted in such a way as to minimize any discomfort or suffering both of a physical or psychological nature. In any case, risks of disability, serious harm or death of participants have to be excluded. And if researchers realize, even while doing the experiment, the possibility of such problems, this principle requires the immediate interruption of the study.

(iii) The third principle that can already be derived from the 1947 code concerns the need for the study to respond positively to a risk-benefit analysis, in order to be sure that the degree of risk (to participants) never exceeds the presumed benefits (to science). The result of this analysis may vary depending on the relevance of the outcomes. In any case, each trial must be designed in order to providing results that are useful for improving individual or collective health, and that cannot be achieved by other, less risky means.

iv) The fourth rule for clinical research is about the methodological profiles of the study. Accordingly, the project has to be based on data from previous studies (e.g., animal testing) and has to be designed and conducted in such a way as to give statistically appreciable results and not merely random sequences. Also, the research has to be designed, and the structures involved organized in such a way as to ensure the minimization of risks, even the most remote ones. Each phase of the study, moreover, has to be conducted by qualified and adequately trained personnel.

v) In addition to the four mentioned principles, which are part of the original law and ethics of human experimentation since the Nuremberg code, a fifth principle has been indicated: each study must be articulated within a protocol examined by an independent IRB or ethics committee. In the Declaration of Helsinki, the World Medical Association has promoted since the first version (1964) the intervention of an ad hoc independent committee for consideration, comment and guidance, then formalizing the necessary evaluation by an independent body (1975). In today's version, Article 23 of the Declaration provides as the following:

> «The research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence and must be duly qualified. It must take into consideration the laws and regulations of the country or countries

in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration.
The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions». (See: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/.)

Although EU countries have different regulations, these five principles can be considered, to a certain extent, the common core of the European law on medical research and clinical trials.
In the near future, in any case, a new regulation (EU No 536/2014) will be finally implemented and applied all over EU. In fact, although the regulation officially entered into force on 16 June 2014, the timing of its application depends on the development of a fully functional Clinical Trials Information System (CTIS), based on a clinical trials portal and a database which have not yet been established. After a number of extensions, the deadline for its application is now fixed for December 2021 (https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trial-regulation).
The Regulation focuses on a number of topics and rules. On the one hand, it will ensure a greater level of legal harmonisation for conducting clinical trials throughout the EU. For instance, it will introduce an authorisation procedure based on a single submission via the portal, and an assessment procedure leading to a single decision. The Regulation also confirms and clarifies the rules on the protection of subjects, informed consent, and transparency requirements. On the other hand, Regulation 536/2014 will make it easier for pharmaceutical companies to conduct multinational clinical trials, which should increase the number of studies and financial investments in the EU (https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/regulation5362014_qa_en.pdf).

II. Selected materials

Relevant legislation and other documents

Nuremberg Code:
https://history.nih.gov/display/history/Nuremburg+Code

Belmont Report:
https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

Helsinki Declaration:
https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

Italian National Bioethics Committee, *La sperimentazione biomedica per la ricerca di nuovi trattamenti terapeutici nell'ambito della pandemia covid-19: aspetti etici* (3 novembre 2020) http://bioetica.governo.it/italiano/documenti/pareri-e-risposte/la-sperimentazione-biomedica-per-la-ricerca-di-nuovi-trattamenti-terapeutici-nell-ambito-della-pandemia-covid-19aspetti-etici/

Regulation (EU) N. 536/2014: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/regulation5362014_qa_en.pdf

Selected bibliography

Annas G.J., Grodin M.A., *The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation*, New York, 1992

Appelbaum P.S., Roth L.H., Lidz C., *The therapeutic misconception: Informed consent in psychiatric research*, in *International Journal of Law and Psychiatry*, 1982, 5 (3–4): 319-329.

Beauchamp T.L., Childress J.F., *Principles of Biomedical* Ethics, Oxford University Press, 1979.

Casonato C., *I farmaci, fra speculazioni e logiche costituzionali*, in *Rivista AIC*, 2017/4.

Casonato C., Tomasi M., *Diritti e ricerca biomedica: una proposta verso nuove consonanze*, in *Biolaw Journal*, 2019, 1: 343-358

Garattini S., Bertelé V., *Farmaci sicuri*, Edra, 2018. Recensione in: Recenti progressi in medicina.

Harris J., *Scientific research is a moral duty*, in *Journal of Medical Ethics*, 2005, 31: 242-248

Jones J.H. , *Bad blood. The Tuskegee Syphilis experiment*, The Free Press, 1993

Petrini C., Brusaferro S., *Ethics committees and research in Italy: seeking new regulatory frameworks (with a look at the past)*, in *Annali dell'Istituto Superiore di Sanità*, 2019, Vol. 55, No. 4: 314-318.

Petrini C., Garattini S., *Trials, Regulation and tribulations*, in *European Journal of Clinical Pharmacology*, 2016, Vol. 72, No. 4: 503-505

Petrini C., *Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use: an overview*, in *Annali dell'Istituto Superiore di Sanità*, 2014, Vol. 50, No. 4: 317-321.

Reverby S.M., *Examining Tuskegee: The Infamous Syphilis Study and Its Legacy*, University of North Carolina Press, 2009.

Social determinants of health:
Health in All Policies, behavioural sciences and nudging

Simone Penasa

I. Introduction

Two key-data can be recalled when approaching the issue of the use of science, and especially behavioural sciences, and public health policies. On the one hand, health's level is primarily linked to non-health factors, such as social, cultural, economic ones. On the other hand, individual choices are always conditioned by concrete characteristics of the context and conditions in which they are made.

Epidemiological data: social inequalities and health conditions

According to EuroHealthNet data for 2019 (Report "Health Inequalities in Europe") life expectancy at birth considerably varies between European Union Member States. If in Bulgaria life expectancy average is 74.8 years, in Spain it reaches 83.4 years. If we focus on healthy life years remaining at 65 years, within an EU average of 9.8 years for men and 10.2 years for women, there are big gaps between Member States, as the range varies from 3.8 years (men) and 4.1 (women) years in Slovakia to 15.4 and 15.8 years in Sweden. With regard to self-perceived health in the EU, the 80.4% of the 20% of the richest population in the EU considers its health as "good or very good", while within the 20% of the poorest population only 61.2% expresses the same feeling. Furthermore, people with lower levels of education have a higher risk of suffering from certain diseases than those with a high level of education. More precisely, 3.12 times higher of suffering depression, 2.36 higher for diabetes and 1.93 for obesity. According to the WHO Health Equality Status Report, 90% of health inequalities are explainable by financial insecurity (35%), poor quality housing and neighbourhood environment (29%), social exclusion (19%) and lack of decent work and poor working conditions (7%). Therefore, only 10% of health inequalities depends from the quality of health care of a given State.

The role of social determinants of health: The Health in All Policies (HiAP) approach

Referred data confirm that many factors have an influence on health in addition to a person's individual genetics and lifestyle. They are personal, social, economic and environmental factors, such as income and social status, employment and work conditions, education, childhood experiences, social support networks, personal behaviours, gender and culture. Thus, social determinants of health refer to "the social and economic (or 'socioeconomic') factors that relate to a person's place in society, such as education, occupation or income" (European Parliamentary Research Service, Addressing health inequalities in the European Union. Concepts, action, state of play, 2020).

Before this evidentiary background, political institutions at both European and national level started to adopt institutional and legal strategies in order to tackling non-sanitary prerequisites of individual and public health. One of the more effective regulatory tool is represented by the Health in All Policies (HiAP) approach, which "seeks to improve health and at the same time contribute to the well-being and the wealth of the nations through structures, mechanisms and actions planned and managed mainly by sectors other than health". This strategy is grounded on the solid the solid evidence that health can be influenced by policies of other sectors, and that health has, in turn, important effects on the realization of the goals of other sectors, such

as economic wealth, and aims to help strengthen this link between health and other policies (Ståhl, Wismar, Ollila, Lahtinen, Leppo (Eds.), Health in All Policies. Prospects and potentials, Ministry of Social Affairs and Health, Finland, 2006). According to the WHO, Helsinki Statement on HiAP (2013), «an approach to public policies across sectors that systematically takes into account the health implications of decisions, seeks synergies, and avoids harmful health impacts in order to improve population health and health equity» and "It improves accountability of policymakers for health impacts at all levels of policy-making", by putting an emphasis on the consequences of public policies on health systems, determinants of health, and well-being. Thus, the ultimate aim of HiAP is "to enhance evidence-informed policy-making by clarifying for decision-makers the links between policies and interventions, health determinants and the consequent health outcomes".

At the EU level, HiAP strategies are channelled mainly through soft law tools, taking into account also the limited competencies in the field of health (see arts. 9 and 168 TFEU and art. 34 CFREU). The institutional inception was the first Finland's Council Presidency, which is the State where this strategy has the longest and more consolidated tradition. Council Conclusions on "Equity and Health in All Policies: Solidarity in Health" (2010) acknowledged the strict link between social conditions, inequalities and stated that further information on the social determinants of health is needed to guide policies towards equity in health. Since then, nutrition and physical activity, alcohol, tobacco have been one of the target of regulatory and political action of EU institutions.

Behavioural sciences (BS) and the nudging: regulatory tools for improving effectiveness of health-related public policies

The implementation of behavioural sciences methods and tools to public policies is one of the most innovative approaches to social activities which can produce an impact on individual and public health. BS can be defined as the application of a more nuanced and evidence-based understanding of human behaviour to inform policy-making process. The use of BS into policy-making is based on the idea that consumers and citizens do not behave rationally and thus it assumes the presence of systematic violations of rationality in human thought (X. Troussard, R. van Bavel, How Can Behavioural Insights Be Used to Improve EU Policy?).

Accordingly, the connection between BS and public policy is the expression of the broader relationship between science, polity and law, as "Behavioural public policy (…) includes all means and modes of public policy aiming at influencing individual or collective behaviour by using insights from behavioural economics, behavioural sciences, psychology or neurosciences" (Handbook of Behavioural Change and Public Policy). In this regulatory context, scientific expertise becomes an essential resource for governing, as it is included within the decision-making process in order to establish and provide the scientific evidence for the behavioural change agenda.

Within this framework, nudging represents the most known and implemented tool. According to Thaler and Sunstein (2008), nudge is «any aspect of the choice architecture that alters people's behaviour in a predictable way without forbidding any options or significantly changing their economic incentives». Its essential characteristics are that it must be easy and cheap to avoid, non-mandatory and cannot reduce in theory human agency since freedom of choice is not removed.

From this perspective,

"Nudges are distinct from other forms of paternalistic policy instruments or regulation: for example, a tax on sugar or a cap on the size of soda drinks may be inspired by the same

behavioural insights as a nudge, that is, the effectiveness of redesigning the options individuals are presented with. However, the former are not nudges as they reduce the freedom of choice of individuals, are based on a regulatory intervention and have financial implications for citizens. A tax or a prohibition on products reshapes decision-making by effectively reducing the options consumers are given. Instead, a product placed at eye-level or a pre-filled in form are more convenient products but nothing impedes consumers from preferring an alternative" (S. Ranchordàs, Nudging citizens through technology in smart cities, in International Review of Law, Computers & Technology, 34:3, 2020).

Nudge aims to intervene on social choice architecture, assuming that the context in which individuals make choices can influence the way they think and the decisions they make. Thus, if you change the context in which individuals decide, you will also influence the content of their decisions. In the context of public policies,

"where the state pursues policies aimed at influencing the decisions that its citizens make regarding their health, it becomes a choice architect for its citizens' health. Such policies need not be confined to institutions whose main business is health (or health care). It might include initiatives which have health effects, even if they are based in other state run departments such as food, agriculture, or transport. For example, making bicycles available through public hire schemes may alter social norms and nudge people to cycle rather than taking other transport".

Nudge's theoretical ground put together the idea of paternalism, because 'it is legitimate for private and public institutions to attempt to influence people's behaviour' and 'steer people's choices in directions that will improve the choosers' own welfare', and libertarianism, "since this ought to be done in a way that preserves 'freedom of choice on grounds of either autonomy or welfare" (M. Quigley, Nudging for Health: On public policy and designing choice architecture, in Medical Law Review, 2013).

Possible critics to this method are related to three dimensions. First dimension is related to the selection of what must be considered "the best option" for individuals ("How can someone (public officials, companies, physicians) legitimately claim to know what is good for another (citizens, employees, patients)?"). Second dimension refers to the behavioural techniques employed, as "even if nudges leave all options on the table, they intentionally and successfully induce bad reasoning and manipulate people and pervert their choices". Third frame of objections refers to who is doing nudging, in the sense that there is a nudging agent (policymaker, government agency, company) who is deliberately steering other people's decisions (B. Engelen, Ethical Criteria for Health-Promoting Nudges: A Case-by-Case Analysis, in The American Journal of Bioethics, 19(5), 2019).

A paradigmatic case: The Behavioural Insights Team (United Kingdom)

United Kingdom is probably the most relevant experience of effective and systematic implementation within public policies of behavioural sciences. It was established as "Nudge Unit" within the UK Cabinet Office in 2010 and became an independent social purpose company in 2014 as Behavioural Insights Team (BIT). It continues to collaborating with the UK Government and local authorities by providing independent research and experimenting concrete actions based on the nudge theory in many areas of public life, such as health, education, taxation. The general aim is to translate the best of behavioural science into policy and practice. A case of implementation of BS in health-related context is a project aimed to tackling childhood obesity, which represents a relevant issue in UK (one in five children re overweight or obese by age 11). By using the evidence that environment where children live matters as much as individual choices when it comes to how they eat, in 2013 BIT in

collaboration with the Department of Health and Social Care proposed to intervene on the UK's sugar tax mechanism in order to link it to the level of sugar contained in market-leading products. The idea was to set sugar thresholds able to "push" industry to reformulate to meet it, by substituting sugar without compromising the consumer price or quality of popular drinks. The outstanding outcome of this "experiment" was that, even before the entry into force of the tax (2018), popular brans made substantial improvements, resulting in an 11% reduction of sugar in soft drinks, which is the equivalent of removing 10,000 tonnes of sugar from UK shelves (see BIT Annual Report 2017-18).

II. Selected materials

Relevant legislation and other documents

Social determinants of health

The 8th Global Conference on Health Promotion, Helsinki, Finland, 10-14 June 2013, The Helsinki Statement on Health in All Policies

Council Conclusions on "Equity and Health in All Policies: Solidarity in Health" (2010)

EuroHealthNet, Report "Health Inequalities in Europe", 2019

European Parliamentary Research Service, Addressing health inequalities in the European Union. Concepts, action, state of play, 2020

Health in All Policies (HiAP) Approach

WHO, Progressing the Sustainable Development Goals through Health in All Policies. Case studies from around the world , 2017

Selected bibliography

Social determinants of health

Donkin A, Goldblatt P, Allen J, et al, Global action on the social determinants of health, in British Medical Journal Global Health, 2018, 3

Health in All Policies (HiAP) Approach

T. Stahl et al., Health in All Policies: Prospects and potentials, 2006

T. Stahl, Health in All Policies: From rhetoric to implementation and evaluation - the Finnish experience, in Scandinavian Journal of Public Health, 2018

S. Penasa, La 'salute in tutte le politiche': presupposti teorici e fondamento costituzionale, in Federalismi.it, 2015

Behavioural sciences/Nudging

H. Straßheim, S. Beck (eds.), Handbook of Behavioural Change and Public Policy, Elgar, 2019

C. Sunstein, L. Reisch, J. Rauber, Behavioral Insights All Over the World? Public Attitudes Toward Nudging in a Multi-Country Study, SSRN, 2017

M. Quigley, Nudging For Health: On Public Policy And Designing Choice Architecture, in Medical Law Review, Volume 21, Issue 4, 1 December 2013

P. Hansen, The Definition of Nudge and Libertarian Paternalism: Does the Hand Fit the Glove?, in European Journal of Risk Regulation, 2016

R. Thaler, C. Sunstein, Nudge: Improving Decisions About Health, Wealth and Happiness, Penguin, 2009

S. Ranchordàs, Nudging citizens through technology in smart cities, in International Review of Law, Computers & Technology, 34:3, 2020

M. Quigley, Nudging for Health: On public policy and designing choice architecture, in Medical Law Review, 2013

B. Engelen, Ethical Criteria for Health-Promoting Nudges: A Case-by-Case Analysis, in The American Journal of Bioethics, 19(5), 2019

X. Troussard, R. van Bavel, How Can Behavioural Insights Be Used to Improve EU Policy?. Intereconomics 53, 8–12 (2018)

H. Straßheim, S. Beck (eds), Handbook of Behavioural Change and Public Policy, Elgar, 2019

Further useful links

Commissione Europea - DG Health and Food Safety - Public Health

WHO/Europe, Social Determinants

OECD, Behavioural insights

The Behavioural Insights Team, UK

Health in All Polices Task Force, California (US)

Behavioural Insights-EU Science Hub (EU)

Cross-border healthcare and patients' mobility

Lucia Busatta

I. Introduction

Cross-border healthcare is a significant example of the tight interlace of EU and State competences in the field of healthcare. It could be defined as the right of an individual patient to obtain medical treatments in a Member State (MS) different from the one in which she is medically insured and to receive reimbursement for medical expenses incurred abroad from her home healthcare institution. It could also describe the possibility for a healthcare service provider to exercise in another MS. In any of these possibilities, the conditions under which cross-border mobility for healthcare is possible are set by EU rules and derive both from the Treaties provisions and from EU legislation.

In this chapter, we will mainly focus on patients' mobility, which is frequently referred to in terms of "medical tourism", even though the latter expression is not apt to correctly describe the phenomenon. By medical tourism, in fact, we make reference to the possibility to travel abroad to get medical services, but normally the related expenses are directly paid by the patient and there is no link with either the hosting or the home healthcare institution. On the contrary, cross-border healthcare does refer to patient's getting medical treatment abroad but within a legal scheme designed by EU legislation. Firstly, individuals' mobility is limited to the EU territory, that means that medical care could be obtained only in another Member State, whereas medical tourism could comprehend also third countries. Secondly, treatments that could be covered are only those that are already included in the list of treatments available within the home healthcare institution, therefore a patient cannot get a treatment that is not already provided by her healthcare service of affiliation. Furthermore, depending on the legal scheme applicable, the treatment concerned is paid by the healthcare institution of affiliation (i.e. the one of the State where the individual patient is resident or registered), either directly or by reimbursement of medical expenses to the patient. In order to fulfil the requirements that permit to the home health institution to take charge of medical expenses incurred abroad, the individual patient must meet some features that are provided by the EU law.

Therefore, EU law on cross-border healthcare runs on two parallel tracks, that should be taken into consideration to have a complete overview on the regulation of the phenomenon. The first one is the European Parliament and Council Regulation (EC) 883/2004 of 29 April 2004 on the coordination of social security systems, which replaced Regulation 1408/71, and which is generally aimed at facilitating the free movement of EU workers and their families. The second track is the Directive on patients' mobility (European Parliament and Council Directive 2011/24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare), which came after almost ten years of litigation before the European Court of Justice (CJEU) with the aim of harmonising the very different national legislations on the possibility to get medical care in another MS at the expenses of the healthcare institution of affiliation.

More precisely, art. 20 of the Regulation provides that «An insured person who is authorised by the competent institution to go to another Member State with the purpose of receiving the treatment appropriate to his/her condition» shall receive that treatment as though she were insured there. «The authorisation shall be accorded where the treatment in question is among the benefits provided for by the legislation in the Member State where the person concerned

resides and where he/she cannot be given such treatment within a time limit which is medically justifiable, taking into account his/her current state of health and the probable course of his/her illness». This provision, however, was quickly exploited to take advantage of the Treaty's provisions on internal market and on the freedom to provide and receive services in the EU territory and, in particular, leaning on Art. 56 TFEU (previously Article 49 TEC), which prohibits restrictions on the freedom to provide services in the EU. Since 1968, in *Luisi and Carbone* decision (Joint cases C-286/82 and C-26/83 *Luisi and Carbone* [1984] ECR I- 00377. ECLI:EU:C:1984:35), the CJEU has stated that medical treatments must be considered as services under the Treaty provisions.

In other words, claiming the rights deriving from internal market freedoms, individual patients started to challenge State restrictions on their possibility to travel for medical services. Taking into consideration cases in which individual patients were refused the authorisation provided by the Regulation, the CJEU started to set and progressively specify a set of rules that allow for State restrictions on the freedom to provide services and benefit of treatments. In *Kohll*, in 1998 (C-158/96 Kohll [1998] ECR I-01931. ECLI:EU:C:1998:171), the CJEU found that the system of prior authorisation is a restriction on the freedom to provide services and that the Regulation provisions do not impede to MS to reimburse the costs for medical expenses sustained by EU patients in a Member State different from the one of affiliation. Restrictions on the freedom to provide services could only be justifiable on grounds of public health in order to protect the quality of internal medical services (that is the need to maintain a balanced hospital and medical service open to all). In the concrete case, this condition was not met, and the restriction was found unjustified.

A few years later, in the landmark *Watts* case (C-372/04 Watts [2006] ECR I-04325. ECLI:EU:C:2006:325), the CJEU went on further in specifying this principle, to the point that it stated that the refusal of prior authorisation cannot be justified on the mere existence of waiting lists in the health service of affiliation. To solve the case, the Court of Justice analysed in depth the organisation of the English health service, which is completely publicly funded and universalistic in nature (i.e. individuals affiliated to the service are all equal in point of access to healthcare treatments and clinical priorities are dealt through waiting lists). As a result, EU judges gave a strong contribution to the definition of undue delay in access to a medical treatment, as a reason for cross-border healthcare, saying that it has to be considered with reference to the individual patient's clinical needs.

As an aftermath of the decision, the EU legislature began working on a Directive to harmonise national rules and to give legislative shape to the principles progressively established by the Court of Justice. The Directive on patient's rights in cross-border healthcare was finally approved in 2011 and outlines the circumstances in which MS may lawfully restrict freedom of movement for medical treatments, which remains the general rule following the internal market Treaty provisions. The Directive defines in legislative terms the exception to this general rule, providing for a detailed procedural framework that today regulates cross-border healthcare provisions in the whole EU territory. In few words, patients can obtain medical treatments in another MS and being reimbursed afterwards mainly freely, unless they need highly specialised or hospital care. In this case, they need to obtain from the healthcare institution of affiliation a prior authorisation. The Directive also creates National Contact Points, to provide information on cross-border healthcare; it boosts the cooperation among MS in key areas such as the treatment of rare diseases and telemedicine through European Reference Networks and encourages the exchange of good practices among MS. Above all, the main scope of the Directive was to stop litigation before the CJEU and to definitely clarify the rules

concerning healthcare abroad. It should be pointed out that, as provided by recitals of the Directive, the Regulation on the coordination of national security systems is still the prevailing legal scheme and should take prevalence when a patient meets the condition for both the regulation and the directive (recitals 28-31). Therefore, the Directive framework has a residual nature.

Indeed, after the Directive was adopted, the litigation before the Court of Justice has substantially halted, with the only exception of requests for preliminary references based on pre-existing cases (that brought, for example, to the *Petru* decision in 2013) and to secondary issues concerning the mutual acknowledgement of medical prescriptions.

The phenomenon of cross-border healthcare, taken as whole, represents a very good example of several interactions between State and EU roles and competences that are at the centre of the current legal debate. Firstly, cross-border healthcare demonstrates that, even though the EU does not have direct competence over the organisation of healthcare services, it still can significantly influence state provisions on treatments and services. Secondly, it touches the delicate chords of the enduring tensions between EU and state legal discipline on social rights: enforcing EU Treaties and giving shape to its principles is more and more requiring states' action on social rights and, therefore, a strong public economic commitment on the granting of services. Thirdly, it is strictly linked with the realisation of the principle of solidarity that, in several fields, has been challenged and questioned by states forced to enact policies and regulations to fulfil EU obligations. In this specific sector, solidarity is also boosted among MS, through the request of sharing good practices and to cooperate in the organisation of health services. Fourthly, as to the organisation of healthcare services and their interoperability, the discipline governing the right to obtain medical care around the EU at the expense of the home health institution could be considered a first step towards a more general integration of national health services. Finally, the ongoing pandemic emergency that is bending most European countries has demonstrated to all of us the essential need for a strong and structured cooperation among MS in the field of healthcare, which is the only concrete solution to be prepared and seriously face global health challenges.

II. Selected materials

Relevant legislation and other documents

Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems - ELI: http://data.europa.eu/eli/reg/2004/883/2014-01-01

Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare - ELI: http://data.europa.eu/eli/dir/2011/24/oj

Communication from the Commission (2020/C 111 I/01): Guidelines on EU Emergency Assistance on Cross-Border Cooperation in Healthcare related to the COVID-19 crisis

Periodic report on the implementation of the Directive: Member State Data on cross-border healthcare – Year 2017

Relevant case-law

C-158/96 Kohll [1998] ECR I-01931. ECLI:EU:C:1998:171
C-120/95 Decker [1998] ECR I-01831. ECLI:EU:C:1998:167
C-368/98 Vanbraekel [2001] ECR I-05363. ECLI:EU:C:2001:400
C-157/99 Smits e Peerbooms [2001] ECR I-05473. ECLI:EU:C:2001:404
C-385/99 Müller-Fauré e van Riet [2003] ECR I-04509. ECLI:EU:C:2003:270
C-56/01 Inizan [2003] ECR I-12403. ECLI:EU:C:2003:578
C-145/03 Keller [2005] ECR I-02529. ECLI:EU:C:2005:211
C-372/04 Watts [2006] ECR I-04325. ECLI:EU:C:2006:325
C-444/05, Stamatelaki [2007] ECR I-03185. ECLI:EU:C:2007:231
C-466/04 Herrera [2006] ECR I-05341. EU:C:2006:405
C-211/08 Commission v Spain (Major Medical Equipment) [2010] ECR I-05267. ECLI:EU:C:2010:340
C-173/09 Elchinov [2010] ECR I-08889. ECLI:EU:C:2010:581
C-255/09 Commission v Portugal (Non-Hospital Medical Care) [2011] ECR I-10547. ECLI:EU:C:2011:695
C-490/09 Commission v Luxembourg (Medical Laboratory Tests) [2011] ECR I-00247. ECLI:EU:C:2011:34
C-562/10 Commission v Germany (Care Equipment) [2012] ECLI:EU:C:2012:442
C-268/13 Petru [2014] ECLI:EU:C:2014:2271

Selected bibliography

Boggero G., Gli ostacoli alla mobilità transfrontaliera in Italia, in Corti Supreme e Salute, 2, 2018, 277 ss.

Busatta L., La cittadinanza della salute nell'Unione Europea: il fenomeno della mobilità transfrontaliera dei pazienti, dalla libera circolazione alla dimensione relazionale dei diritti, in DPCE Online, 3, 2015

Busatta L., Carenze sanitarie e mobilità transfrontaliera: si allarga il diritto "europeo" alla salute Nota alla sentenza C-268/13, Petru, Corte di Giustizia dell'Unione Europea, in DPCE Online, 1, 2015

de La Rosa S., The directive on cross-border healthcare or the art of codifying complex case law, in Common Market Law Review, 49, 2012, 15-46

Flear M.L., Developing Euro-Biocitizenship through migration for healthcare services, in Maastricht Journal of European and Comparative Law, 14(3), 2007, 239 Frischhut M., Fahy N., Patient Mobility in Times of Austerity: A Legal and Policy Analysis of the PetruCase. European Journal of Health Law, 23(1), 2016,36–60

Hervey T., McHale J., European Union Health Law. Themes and Implications, Cambridge University Press, 2015 , 71-97; 184-210

Newdick C., Citizenship, free movement and health care: Cementing individual rights by corroding social solidarity. Common Market Law Review, 43(6), 2006, 1645–1668

Further useful links

Official page on the website of the EU: Cross-border healthcare https://ec.europa.eu/health/cross_border_care/overview_en
European Reference Networks: https://ec.europa.eu/health/ern_en

Current issues in the protection of genetic data and biobanking in the EU

Marta Tomasi

I. Introduction

The complex and manifold relationship between genetics and law has lively evolved over the years, often attracting the attention of jurists and bioethicists.
The applications of genetics, in fact, call into question a plurality of areas of law, depending on whether genetic information is used for diagnostic, therapeutic, individual identification purposes, in the medical, procedural, insurance, employment or school field, and much more. Since the conclusion of the Human Genome Project in 2003, which led to the first complete mapping of the human genome, the main concerns have addressed the possible risks of discrimination arising from the use of particularly sensitive information and the need to protect people's fundamental rights such as privacy and confidentiality.
It is important to highlight the fact that the advancement of knowledge in the field of genetics has somehow helped to reduce lawyers' concerns or, at least, to reorient their focus. Over the years, in fact, some notions such as *exceptionalism* and *determinism* have lost consistency. *Determinism*, which claims to sum up the biological identity of the human being in its genetic component, comes today to terms with the increasingly consolidated scientific knowledge on the plurality of factors connected to the biological life of each individual and the interrelationships between them (think, for example, of epigenetics). In the same way, *exceptionalism*, which sees genetic data as a very peculiar entity characterized by distinct nature from other sensitive information, is based on elements that have at least in part been called into question. For example, one of the elements that for a long time represented a connotative trait of genetic information, that of its non-modifiability, has lost consistency in recent years, due to the development of technical capabilities to intervene on the DNA of living beings, modifying and "improving" it (think of the promising CRISPR-Cas9 gene editing technique).
These adjustments, however, have not diminished the degree of interest that this field of knowledge holds for the law and, on the contrary, have increased it. Despite its sectoral character, there are many profiles that make this field particularly significant for biolaw studies. The first reason of interests is that, unlike other revolutions that have turned out to be broken promises, genetics has been redesigning the world of medicine and research on a daily basis for the past 20 years, and even if the definitive scenario of a geneticisation of medicine is neither plausible nor desirable, it is likely that in the years to come its importance will increase rather than decrease. This encouraging scenario also depends on the possibility for this science to benefit from the very fast advances of some technologies, whose point of arrival is not yet foreseeable (think of the advances in sequencing techniques and the increased capacity of data analysis).
The second aspect is given by the fact that, being linked to identity profiles, in some cases on the basis of scientifically objective elements (think of the cases of single-gene diseases, such as Huntington's disease or sickle cell anemia), in other cases on the assumption of elements linked to a mere perception or social construction (think of the highly contested and current notion of "race"), genetics has had a problematic relationship with public power throughout history. Moreover, perhaps for this very reason, in contrast to what happened with regard to other

technological advances, the law has taken prompt action to contain the risks and dangers associated with this branch of knowledge, in some cases – as mentioned above – also overestimating them. A further reason of importance, maybe less noble, but nevertheless real, is that of economic interests, which are evident when considering the importance of personal data in modern society, which have recently been defined as "the new oil" (the genetic testing market accounted for over USD 12 million in 2019, and is expected to almost duplicate its value by 2027).
Even limiting the field of analysis to issues related to medicine and scientific research, all the reasons described above give a central role to the study of the modifications that genetics has produced on the constitutional status of the person in the field of biomedicine and of the consequences in terms of the configuration and effectiveness of rights involved. The legal image of the person, and the set of rights involved, must be reconsidered under three dimensions of 'relationship', 'space' and 'time'.

To this aim, the starting point of the reasoning is the connatural ambivalence of genetic data which gives concreteness to the unrepeatability and uniqueness of the human being and at the same time interweaves relationships among people sharing the same DNA. The fact that the human genome is shared with other individuals imposes to detach from the scheme of individual subjectivity, which underpins the theories of individual rights. In concrete terms, this implies that the traditional standards of medical confidentiality and privacy clash with an unavoidable need to share personal data and information in the clinical and scientific research fields. Thus, for example, the general principle of confidentiality of the relationship with the doctor has found regulatory exceptions to guarantee the interests of third parties belonging to the same biological group. These evolutions are testified, for example by the case of ABC vs. St George's Healthcare NHS Trust, in which the defendants learned that ABC's father suffered from Huntington's disease but, consistent with his wishes, did not disclose the diagnosis to ABC. When ABC was subsequently diagnosed with the same condition she sued the defendants in negligence. The trial judge ordered ABC's statement of claim be struck out on the basis that the Defendants did not owe a duty of care to ABC. However, the Civil Division of the English Court of Appeal quashed that order and remitted the case for trial. In doing so, the Court has left open the possibility that a duty of care may be owed to third parties with an interest in a patient's genetic information, however whether such a duty exists still needs to be determined. Similarly, the strict rules on data confidentiality in the field of scientific research give way, in some cases, to the need for sharing, as indicated, for example by the need of many rare disease patients to distribute their biological samples and personal information to receive a diagnosis or therapeutic solutions.
The field of research clearly shows how the relationships to which genetics attributes importance also extend beyond the boundaries of the family group, bringing to light new issues related to the concept of equality. Many national and international regulations now prohibit discrimination on a genetic basis, but most of the debates focus on two specific areas, insurance and employment. However, we must not forget the many risks of violation of the principle of equality that affect the field of biomedicine today. The most interesting profiles, in this sense, derive from progress in the field of personalised medicine.
The aim of this new branch of medicine is to identify the best treatment for everyone, based on their biological characteristics, with the ultimate aim of overcoming inequities in healthcare and to ensure that everyone can benefit from proper and effective treatments. Nevertheless, the steps that have to be taken to get to that result pave the way towards new risks of

discrimination, due to the need to identify sub-segments of the population to be studied. This task, which is the essential prerequisite to learn how treatments work, has to be based on biological features shared among different individuals. The selection of these elements, which produces a “fragmentation of humanity”, has to be attentively reasoned, since the choice of a wrong proxy for genetic features can easily lead to dangerous consequences.
The most patent example of these risks is racial medicine. In some cases, it happened that race – a non-existing category in human biology – has been used to categorize patients, pretending that their genetic makeup proved to specifically benefit from the new treatment developed. This is what happened in the case of Bidil, the first racial drug approved by the FDA in 2006. The approval of a drug which is supposed to work for people belonging to a specific racial group risked to convey the message that race is real, re-opening the way to old discriminations.
And even if groups are properly designed the risk is that not everyone will be able to benefit equally from these advances. Research has shown that most of the genetic knowledge we have is based on the genomes of a select group of individuals. According to a recent analysis, an estimated 78% of genomes in genome-wide association studies (GWAS) are from people of European descent, meaning that the majority of genetic information we have is only accurate for a small portion of the global population and forget to address medical problems that cause the most morbidity and mortality in developing nations.
This data bias has created and, unless the trend changes, will create healthcare disparities that have left a large part of the global population behind.

In addition to this relational dimension, new dimensions of time and space must be taken into account as well. Genetics promotes an idea of health and healthcare that – thanks to the predictive nature of genetic information - extends throughout a lifetime. Moreover, genomic research can be carried out, starting from the same materials and data, in different moments also far in time. These considerations prevent the person, patient or participant, and his/her rights from being considered in a punctiform way along the line of time but requires them to be taken into account in their diachronic essence. Secondly, from a spatial point of view, the collections of samples and data and, in particular, biobanks, allow frequent transfers of biological materials and data, giving them a global relevance. The traditional boundaries of jurisdictions, therefore, are challenged by the accessibility of new technologies on a global level and the possibility of extending the 'informational dimension' of the person into virtual space. Furthermore, these considerations impact, in particular, on one of the instruments traditionally intended to protect confidentiality and self-determination in the field of biomedicine: informed consent. This tool, in the field of genetics – either clinical or research – has to been deconstructed and reinterpreted: the described new dimensions of time and space require to abandon its understanding as an instant authorisation to process data and use them to specific aims and to requalify it in terms of a relational, progressive, and dynamic process, which also promotes a dimension of active participation and responsibility towards oneself and others
These are just a few examples of how genetics solicits, on a daily basis, legal thinking.
In a broader and conclusive perspective, this peculiar field of science also allows some general reflections on the role of law in science regulation and on the "quantity" of biolaw that might be considered appropriate and efficient.
For example, a new role for the law, in these circumstances, beyond establishing detailed legal rules and prohibitions, can work on the creation of more direct contaminations with science and ethics. The idea might be that of a "principled law", based on fundamental (constitutional) principles, integrated with the contribution of other sciences. The self-regulation of the

scientific community at supranational level, for examples, could help integrating and completing the regulatory system, allowing the overcoming of the narrow national regulatory boundaries, which are not well suited to the described extension of the area of physical, informational, and consequently legal relevance of the person within the context of genetic medicine (in this sense, consider the opening of the GDPR toward ethical standards in orienting the scope of
data processing for scientific research).

II. Selected materials

Relevant legislation and other documents

EU General Data Protection Regulation (GDPR - Regulation (EU) 2016/679)
US Genetic Information Nondiscrimination Act (2008)
Italian Data Protection Authority, Provvedimento recante le prescrizioni relative al trattamento di categorie particolari di dati (Authorization n. 146/2019)
Universal Declaration on the Human Genome and Human Rights (Unesco, 11 November 1997)
International Declaration on Human Genetic Data (Unesco, 16 October 2003)

Relevant case-law

ABC v St George's Healthcare NHS Trust & Ors [2020] EWHC 455 (QB) (28 February 2020)

Selected bibliography

J. Bovenberg, D. Peloquin, B. Bierer, M. Barnes, B.M. Knoppers, How to fix the GDPR's frustration of global biomedical research, Science, Vol. 370, Issue 6512, pp. 40-42

R. Brownsword, M. Llewelyn, W. Cornish, *Law and Human Genetics: Regulating a Revolution*, Oxford, 1999

C. Casonato, M. Tomasi, Diritti e ricerca biomedica: una proposta verso nuove consonanze, in BioLaw Journal, 1/2019

J.P. Cerdeña, M.V. Plaisime, J. Tsai, From race-based to race-conscious medicine: how anti-racist uprisings call us to act , Lancet, 396, 2020, 1125–1128

G. Laurie, Genetic privacy: a legal perspective, Glasgow, 1997

M.A. Rothstein, *Reconsidering the duty to warn genetically at-risk relatives*, in *Genetics in Medicine*, 20, 3, 2018, 285

G. Sirugo, S.M. Williams, S.A. Tishkoff, The Missing Diversity in Human Genetic Studies, in Cell, 177, 1, 26-31

M. Tomasi, Principi costituzionali e conoscenze genetiche: verso un nuovo orizzonte di senso per la persona in medicina, in BioLaw Journal, 2S/2019

E. Wright Clayton, B.J. Evans, J.W. Hazel, M.A. Rothstein, The law of genetic privacy: applications, implications, and limitations, in Journal of Law and the Biosciences, Volume 6, Issue 1, October 2019

The rise of Artificial Intelligence in the constitutional dimension

Marta Fasan

I. Introduction

This century is the age of intelligent machines. Every day we find out how deeply Artificial Intelligence (AI) is pervading our lives in numerous ways, performing tasks that we were used to consider an exclusive human prerogative. The development of driverless cars, the growing use of autonomous systems in economic and financial areas, the application of facial recognition technologies in fighting terrorism and in policing operations, the employment of robotic and AI systems for medical and social care's purposes and the rising presence of Artificial Intelligence in the dynamics related to the public and political sphere demonstrate how these technologies are coming out from the science fiction dimension to become relevant factors of real life. The increasing improvements of these technologies and the emerging perspective of their future application highlight the need to better understand this phenomenon, especially taking into consideration the relevant legal consequences of AI employment in our day-to-day life.

The first fundamental step in this general overview of the AI legal dimension concerns the need to understand and clarify what Artificial Intelligence is and what falls within this specific concept. But, even though AI is one of the most important and promising innovation of the contemporary age, there is not an universally and equally shared definition of Artificial Intelligence among experts in the field. Indeed, the uncertainties related to the very concept of intelligence and to the specific subject of this scientific area have led to the deployment of many different definitions of what AI should be. Anyway, in this context of defining pluralism, it's possible to identify the main common features which outline the leading characteristics of the contemporary notion of AI. Taking into consideration the definition adopted by the High-Level Expert Group on Artificial Intelligence of the European Commission, we could define Artificial Intelligence systems as: «*(…) systems designed by humans that, given a complex goal, act in the physical or digital dimension by perceiving their environment through data acquisition, interpreting the collected structured and unstructured data, reasoning on the knowledge, or processing the information, derived from this data and deciding the best action(s) to take to achieve the given goal. AI systems (…) can also adapt their behaviour by analysing how the environment is affected by their previous actions*» (HIGH-LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE, 2019). Thus, Artificial Intelligence is a set of technologies inspired by the ways people use their nervous systems and bodies to sense, learn, reason and take action.

The AI systems' ability to perform intelligent functions is mainly due to two relevant factors: the increase in computational capacity and processing power and the growth in the amount and quality of data available and accessible today. These elements have allowed the development of two learning techniques which play an essential role in making these artificial systems able to produce important results in terms of efficiency: machine learning and deep learning.

The first term refers to a set of techniques that enable the AI system to improve, through experience, the performance of its functions. Based on machine learning, AI can learn and learn through specific examples, collected data and its own experience and, in this way, it can implement the model used to achieve the final given goals (MITCHELL, 1997). On the other hand,

deep learning is a specific type of machine learning which, by imitating the functioning of the human brain, also lets artificial systems to improve their capabilities through experiences and collected data. However, what really characterises deep learning is its functioning's foundation on artificial neural networks, which make the system capable to learn from unstructured and unclassified data, through an unsupervised method. In this way, the AI system can analyse the information and reconstruct data's common correlations and patterns to be used in the final decision-making process (GOODFELLOW, BENGIO, COURVILLE, 2016).

These specific technical features enable AI systems to make accurate, reliable, fast and effective decisions and predictions, enhancing the spread and the application of this technology in many different fields. After all, the growing phenomenon of digitalisation, combined with the learning techniques described above, are facilitating the adoption of AI technologies, considering that the results achieved would be better than those possible with only human work and knowledge. Whether the benefits related to the use of Artificial Intelligence make it desirable to extend this technology more rapidly and pervasively within society, its application is not lacking significant legal consequences. And this, because of the risks involved in using these intelligent tools.

First of all, the development of AI systems rises up important questions about the legal protection of people's right to privacy. As we said before, the operation of these intelligent tools is mostly based on the immense amount of significant data, used to train the artificial system and make it operate in an efficiently way. Therefore, AI researchers and designers have always to collect a sufficient quantity of data from multiple resources, sometimes including also personal and sensitive information. In this context, it's harder to understand who really controls and owns these data, who has the right to access them, who is legitimate to collect personal and private data, how people could effectively give their consent to the use of this kind of information and for which purposes too. And thus, AI deployment could seriously affect the protection of right to privacy and of all its guarantees.

Secondly, the variety and the quality of data employed by AI systems could determine relevant concerning issues. The use of incomplete or biased dataset and of partial information could affect the reliability and fairness of the results obtained through the AI tool. And this possibility would give rise to new forms of discrimination and would perpetuate the already existing ones, also offering a lower performance than normally ensured through standard tools.

Thirdly, the rising digitalisation of many aspects and areas of human social life and the deployment of more and more complex, advanced and intelligent technologies are making harder to ensure equal access to these tools. Both from the economic perspective or from the digital education one, an uncontrolled and unlimited digitalised delivery of public and private services could preclude some people from enjoying the real benefits of these technologies. Such an approach could also fuel dangerous forms of technological divide to the detriment of those individuals who are traditionally considered more vulnerable in our society.

Finally, one of the most problematic issues about AI application concerns the so called black-box phenomenon. The inability to completely understand all the reasons and the logical steps why the AI took that specific final decision could mean a general lack of transparency in certain and fundamental decision-making phases. And this situation is worsened by all that restrictions which significantly limit the access to the source code of the artificial system, protecting the intellectual property rights of the producing companies. In this context, there is a founded risk that such a lack of transparency could undermine people's confidence not only in the reliability of these artificial tools, but also in all those human operators who have the duty to interpret this kind of artificial choices.

By analysing the problematic issues described above, it's evident that the advent of the AI is clearly intended to change human life in the next future with substantial legal consequences in many fields. All the examined matters perfectly outline the risky profiles due to an unsupervised and naïf spread of AI technologies, which could have the undesired consequence of affecting the protection of many fundamental human rights and the application of essential constitutional principles like transparency, equality and self-determination ones. According to this, there is the need to figure out the proper way of introducing AI in the human society and, at the same time, it's necessary to understand how to legally deal with these innovation, considering exactly which legal means could assure an efficient regulation of AI issues. Indeed, the application of these technologies makes us to reconsider the existent traditional legal categories, wondering if they might effectively and sufficiently solve these emerging questions or if it's necessary to create new categories and instruments to face AI deployment in the real world. What we can consider clear in this uncertain scenario, it's the need to set up a regulatory framework aimed at creating and AI for the "Good Society"(CATH ET AL., 2018), even though the improvement of AI systems and their applications are not always driven by the most authentic goal of human progress and wellbeing. Any regulatory action in this field would have to guarantee both the maximization of benefits and the minimization of damages following from the use of intelligent technologies, assuring the protection of human freedoms and rights and avoiding any unjustified fear which could limit the scientific and technological progress. And for this purpose, an effective solution could come from the very original goals of constitutionalism: protection of rights and limitation of powers. Following this direction and the purpose of a reasonable balancing of all the interests involved, many different legal systems are trying to implement a "constitutionally oriented" AI regulation, moving from a wide variety of legal sources and regulatory instruments. And these experiences, although still at an embryonic level, represent a fundamental testing ground to understand which path to take for an effective and human-centred future regulation of Artificial Intelligence.

II. Selected materials

Relevant legislation and other documents

High-Level Expert Group on Artificial Intelligence, *A Definition of AI: Main Capabilities and Disciplines*

High-Level Expert Group on Artificial Intelligence, *Ethics Guidelines for Trustworthy AI*

CEPEJ, *European ethical Charter on the use of Artificial Intelligence in judicial systems and their environment*

European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics

The Queen (on the application of Edward Bridges) (Appellant) v The Chief Constable of South Wales Police (Respondent) & others [2020] EWCA Civ 1058

CNB, CNBBSV, *Intelligenza Artificiale e medicina: aspetti etici*

CNB, CNBBSV, *Sviluppi della robotica e della roboetica*

European Commission, *White Paper on Artificial Intelligence – A European approach to excellence and trust*

Assemblée nationale française, Proposition de loi constitutionnelle relative à la Charte de l'intelligence artificielle et des algorithmes

Assemblée nationale française, Projet de Loi relatif à la bioéthique

OECD, *Artificial Intelligence in Society*
https://www.oecd.org/publications/artificial-intelligence-in-society-eedfee77-en.htm

Consultative Committee of the Convention for the Protection of Individuals with regard to Automatic Processing of Persona Data (Convention 108), *Guidelines on Artificial Intelligence and Data Protection*

Council of Europe, Recommendation CM/Rec (2020)1 of the Committee of Ministers to member States on the human rights impacts of algorithmics systems

Conseil constitutionnel, Décision n° 2018-765 DC du juin 2018

European Union Agency for Fundamental Rights (FRA), *Data quality and artificial intelligence – mitigating bias and error to protect fundamental rights*

Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processin of personal data on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) – art. 22 (Automated individual decision-making, including profiling)

Selected bibliography

Agrawal A., Gans J., Goldfarb A., *Prediction Machines. The Simple Economics of Artificial Intelligence*, Boston, 2018.

Boden M. A., *Artificial Intelligence. A Very Short Introduction*, Oxford, 2018.

Carrozza M. C. et al., *Ai: profili tecnologici. Automazione e Autonomia: dalla definizione alle possibili applicazioni dell'Intelligenza Artificiale*, in *BioLaw Journal – Rivista di BioDiritto*, No. 3, 2019, pp. 237-254.

Casonato C., *The Essential Features of 21st Century Biolaw*, in Valdés E., Lecaros J. A. (ed.), *Biolaw and Policy in the Twenty-First Century. Building Answers for New Questions*, Cham, 2019, pp. 77-91.

Cath C. et al., *Artificial Intelligence and the 'Good Society': the US, EU, and UK approach*, in *Sci Eng Ethics*, No. 2, 2018, pp. 505-528.

Comitato Nazionale per la Bioetica, Comitato Nazionale per la Biosicurezza le Biotecnologie e le Scienze della Vita, *Intelligenza Artificial in medicina: aspetti etici*, Roma, 2020, in

http://bioetica.governo.it/media/4033/6-intelligenza-artificiale_misto-cnb-cnbbsv_it.pdf.
Goodfellow I., Bengio Y., Courville A., *Deep Learning*, Cambridge (MA), 2016.
High-Level Expert Group on Artificial Intelligence, *A Definition of AI: Main Capabilities and Disciplines*, Bruxelles, 2019, in https://ec.europa.eu/digital-single-market/en/news/definition-artificial-intelligence-main-capabilities-and-scientific-disciplines
Hunt E. B., *Human Intelligence*, New York-Cambridge, 2011.
Kurzweil R., *The age of intelligent machines*, Cambridge (MA), 1990.
Leenes R., De Conca S., *Artificial intelligence and privacy – AI enters the house through the Cloud*, in Barfield W., Pagallo U. (ed.), *Research Handbook on the Law of Artificial Intelligence*, Cheltenham-Northampton (MA), 2018, pp. 280-306.
Mattsson T., *Editorial: Digitalisation and Artificial Intelligence in European Healthcare*, in *European Journal of Health Law*, No. 4, 2019, pp. 285-288.
Mitchell T. M., *Machine Learning*, Boston, 1997.
Neisser U., *The Concept of Intelligence*, in *Intelligence*, No. 3, 1979, pp. 217-227.
Nicholson Price II W., *Artificial Intelligence in Health Care: Applications and Legal Implications*, in *The SciTech Lawyer*, No. 1, 2017, pp. 10-13.
Nilsson N. J., *Artificial Intelligence: a new synthesis*, San Francisco, 1998.
Pakin N. G., Lev-Aretz Y., *Learning algorithms and discriminations*, in Barfield W., Pagallo U. (ed.), *Research Handbook on the Law of Artificial Intelligence*, Cheltenham-Northampton (MA), 2018, pp. 88-113.
Scantaburlo T. Charlesworth A., Cristianini N., *Machine Decisions and Human Consequences*, in Yeung K., Lodge M. (ed.), *Algorithmic Regulation*, Oxford, 2019, pp. 49-81.
Scherer M. U., *Regulating Artificial Intelligence Systems: Risks, Challenges, Competencies, and Strategies*, in *Harvard Journal of Law & Technology*, No. 2, 2016, pp. 354-400.
Schönberger D., *Artificial Intelligence in healthcare: a critical analysis of the legal and ethical implications*, in *International Journal of Law and Information Technology*, No. 27, 2019, pp. 171-203.
Stone P. et al., *Artificial Intelligence and life in 2030. One hundred year study on artificial intelligence*, Stanford, 2016, in https://ai100.sites.stanford.edu/sites/g/files/sbiybj9861/f/ai100report10032016fnl_singles.pdf.