ISSN 2704-8012

European Journal of Privacy Law & Technologies

2019/2

G. Giappichelli Editore

European Journal of Privacy Law & Technologies

Directed by Lucilla Gatt

2019/2

G. Giappichelli Editore

European Journal of Privacy Law & Technologies
On line journal
Italian R.O.C. n. 25223

G. GIAPPICHELLI EDITORE - TORINO
VIA PO, 21 - TEL. 011-81.53.111 - FAX 011-81.25.100
http://www.giappichelli.it

The Journal is one of the results of the European project TAtoDPR (Training Activities to Implement the Data Protection Reform) that has received funding from the European Union's within the REC (Rights, Equality and Citizenship) Programme, under Grant Agreement No. 769191.

Published Online by G. Giappichelli in Dicember 2019
www.ejplt.tatodpr.eu

THE IMPACT OF E-HEALTH ON PRIVACY AND FUNDAMENTAL RIGHTS: FROM CONFIDENTIALITY TO DATA PROTECTION REGULATION

Francesco Cirillo

Abstract

This paper aims to address some of the relevant issues of health and privacy within e-health landscape. Scientific progress is actively developing pervasive processing of health data. Once considered as the protection of private life, in the last decades, the concept of privacy has evolved. The main feature is the protection of the flow of personal information in the digital world. The GDPR has introduced a new approach that also entrusts some soft law instruments. The principle of consent has now a different and weaker role. Data-sharing, scientific research, healthcare, privacy and research are placed in a stronger interconnection. In this new framework, deontology and private self-regulation are the ultimate warranty of the balance between health and privacy. Then, the scientific community is entrusted to discover its limits and to be the guardian of a problematic balance between values increasingly transfigured by the disruptive innovation.

Key-words: Privacy, health, e-health, medicine, informed consent, GDPR, scientific research, big data, deep learning, deontology, confidentiality, code of conduct, deliverables, fundamental rights, constitutional law.

Introduction

The purpose of this paper is to address some issues of the relationship between health and privacy, as fundamental rights, in the e-health landscape. [1]

[1] B. Shen (ed.), *Healthcare and Big Data Management* (Springer 2017); C Granja, W Janssen,

New technologies, such as biotech, neurotech and nanotech, have introduced new possibilities in the field of healthcare. [2] The therapy, as a consequence, is no longer limited to removing the disease, but it is extended to the enhancement of human conditions (for example, cosmetic surgery or anti-ageing treatments). The new perspective is well described as a transition from *restitutio ad integrum* to *trasformatio ad optimum.* This new approach to medicine is not limited to the areas of medical intervention, but also includes the use of big data and artificial intelligence in healthcare. [3]

In the empirical model of modern medicine, data collection and data sharing were fundamental activities for scientific progress, and they always involved several risks for privacy and other fundamental rights. [4] The strong connection between scientific progress and processing of health data has now a new role in the context of e-health and big data. Scientific progress is strongly entrusted to innovative and pervasive forms of health data processing. The digitization of health records and some new health care devices have introduced significant changes by using artificial intelligence and data science. [5] Furthermore, in few years we may be connected to an e-health software, which will record our data, concerning health and other personal conditions (e.g. genetic data, consumer life-style data, etc.). Such an e-health system will predict our risks thanks to a general analysis, based on data of other people and then personalized by profiling or by other forms of automated use of data. [6] Likewise, it could analyze and notify for every kind of imperfection with our health, reducing people to a condition that is always pathological and always in need of therapy.

In parallel to healthcare, also privacy is changed: if once it was described just as 'the right to be let alone' [7] (i.e. the safeguard of a private area), in the 'in-

---

MA Johansen, 'Factors Determining the Success and Failure of eHealth Interventions: Systematic Review of the Literature' (2018) 5 J Med Int Res e10235; see also WW Lowrance, *Privacy, Confidentiality, and Health Research* (Cambridge University Press 2012).

[2] R.T. Anderson, C. Tollefsen, 'Biotech Enhancement and Natural Law' (2008) 20 The New Atlantis 79.

[3] N. Mehta, A. Pandit, 'Concurrence of Big Data Analytics and Healthcare: A Systematic Review' (2018) 114 Intern J Med Inform 57.

[4] On the history of modern medicine, EH Ackerknecht, *A Short History of Medicine* (first ed. 1955, John Hopkins University Press 2016); for legal aspects and risks for fundamental rights, H Kupwade Patil, R Seshadri, *Big Data Security and Privacy Issues in Healthcare* (2014) IEEE International Congress on Big Data, Anchorage, AK, 762.

[5] L. Dennison, L. Morrison, G. Conway, L. Yardley, 'Opportunities and Challenges for Smartphone Applications in Supporting Health Behavior Change' (2013) 15(4) J Med Int Res e86.

[6] About the future landscape of e-health, YN Harari, *21 Lessons for the 21st Century* (Random House 2018) Part 1.3.

[7] S.D. Warren, L.D. Brandeis, *The Right to Privacy* (1890) 4 Harv Law Rev 193.

formation society' the idea of privacy turned into something different. We can now define privacy, more than a protection of intimate space, as the protection of the flow of information in the digital world.[8] The General Data Protection Regulation (EU) 2016/679 (GDPR) has introduced a new approach based on the accountability of the players. The controllers «shall implement appropriate technical and organizational measures to ensure and to be able to demonstrate that processing is performed according to this Regulation» (art. 24 GDPR). The meaning is that the controllers have to prove they have planned the mandatory measures for the protection of individual rights. Nonetheless, it is not possible to decipher what these measures should be just by reading the Regulation. It is necessary to link to other legal instruments, such as soft law, communications and other policy instruments, positions of the EU institutions, etc. The approach refers to a trend that characterizes the relationship between public law and new technologies: the innovation needs increasingly soft law instruments.[9]

In particular, the processing of data for medical purposes (e.g. art. 9 GDPR, letters l and i) involves a joint thinking on the issues of medical law, data protection law, data sharing and legal problems of scientific research. Health, privacy and research are placed in ever growing mutual connection. The potential of e-health technology, as well as other new medical intervention techniques, could refer to the bioethical and philosophical issues of posthumanism, which suggest a radical distortion of concepts like therapy, health or disease.[10]

The deontology and self-regulation of the sectors involving this innovation assume the role of the ultimate guarantor of the delicate balance between health and privacy. As we will show in the conclusions, the legal and scientific community will play the specific role of controller of innovation.

1. The impact of new technologies in medical law and bioethics

The first issue we address is that the idea of healthcare is changing. The

[8] As the German constitutional Court stated in 1983, 1 BvR 209/83, in BVerfGE 65, 1-71; on this topic W. Steinmüller, 'Das informationelle Selbstbestimmungsrecht' (2007) 3 FIfF-Kommunikation 15; referring to the Italian legal culture, the first sign of this change already in S Rodotà, *Elaboratori elettronici e controllo sociale* (Il Mulino 1973).

[9] L.G. Trubek, 'New Governance and Soft Law in Health Care Reform' (2006) 3 Ind Health L Rev 139; in Italy, E Tosi, *High tech law: The digital legal frame in Italy* (Giuffrè 2015); in this review, MC Gaeta, 'Hard Law and Soft Law on Data Protection: What a DPO Should Know to Better Perform His or Her Tasks' (2019) 2 EJPLT.

[10] U. Wiesing, 'The History of Medical Enhancement: From Restitutio ad Integrum to Transformatio ad Optimum?', in B. Gordijn, R Chadwick (eds.), *Medical Enhancement and Posthumanity* (Springer 2008) 9.

change mainly relates to what the perception of health is and what therapy should be. Besides this bioethical issue, the power of the new technologies on humans have a huge fallout on legal concepts and fundamental rights. In the continental legal systems, such as Italy, Spain, France or Germany, every person has a broad spectrum of fundamental rights regarding health, healthcare or bodily integrity. [11]

The Italian constitution is the only one that states a general 'right to health' (art. 32 Italian Constitution), a general principle with several meanings. According to the Italian doctrine, there are two different areas of fundamental rights: the freedom in health, which concerns the right to choose the therapy or, in case, to refuse it; then, the right to healthcare, substantially secured in different ways, in different countries and at different times. This distinction reflects the difference of negative liberty (the absence of obstacles to the free will, a kind of continental version of habeas corpus) and positive liberty (the possibility of acting in such a way as to realize one's fundamental purposes), firstly theorized by Isaiah Berlin [12] and in a certain way supported from our doctrine. The 'right to health', the right to 'bodily integrity' and to healthcare, refers to two different meanings of health concept: one is the state in which we are, no matter if good or bad, the other is the state in which we would like to be, a potential future condition. This statement requires reflection on the meaning of the concept of health, because too often it is taken for granted that the term is clear. The World Health Organization, in its Constitution, states that «health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity», [13] but this is a very broad meaning, not so useful in the legal field. As

[11] In Italian Constitution the bodily integrity is linked to the general clause of human rights protection, (*diritti inviolabili*, art. 2), to personal freedom (art. 13) and freedom in healthcare (art. 32), see D. Morana, *La salute come diritto costituzionale* (Giappichelli 2018); likewise, in Spanish Constitution states the *libertad personal* (art.17) and the *derecho a la protección de la salud* (art. 43); in France, there's a mention of health in the Preamble to the Constitution, and in the Charter for the Enviroment, which states that «chacun a le droit de vivre dans un environnement équilibré et respectueux de la santé» (art. 1); also in D. Tabuteau, B. Mathieu, A. Laude, *Droit de la santé* (Presses Universitaires de France 2018); in Germany the *Recht auf körperliche Unversehrtheit* is stated in art. 2 GG, whereas the medical care is linked to the *allgemeine Gewährleistung* of the Government, P Kirchhof, 'Das Recht auf Gesundheit' (2008) na; in United Kingdom, see also M. Weait, 'The United Kingdom: the Right to Health in the Context of a Nationalized Health Service', in J.M. Zuniga, S.P. Marks, L.O. Gostin (eds.), *Advancing the Human Right to Health* (2013) 209; a general perspective in T Degener, M Decker, 'Das Recht auf Gesundheit', in K Walther, K Römisch (eds.), *Gesundheit inclusive*: *Gesundheitsförderung in der Behindertenarbeit* (Springer 2018) 35.

[12] I. Berlin, *Two Concepts of Liberty* (Clarendon 1958); about this distinction in the Italian doctrine, A Pace, *Problematica delle libertà costituzionali* (Cedam 2003) 95.

[13] World Health Organization, *Constitution of the world health organization* (1946), and the

a matter of fact, if we look at the concept of health used in the courts, we will find a concept of health more like bodily integrity, meant as the specific biological state, often still referred to biostatistical conception of health. [14] It is evident that other meanings of health are assumed to distinguish medical care from other kinds of assistance. However, in case of medical care, the health is always the theoretical state in which patient would be, referring to the technological possibilities and to the historical and cultural context. These considerations make it possible to state that health is a relative concept, as it has been demonstrated by the philosophy of medicine. [15] Furthermore, it is possible to state that health has at least two possible general meanings: health as a condition, and health as a goal, whatever they mean.

In a certain way, we could imagine this difference of meaning also as a progressive change of the point of view. Technological innovation in medicine has completely involved the relation to the human body. If two centuries ago, the highest ambition of medical practices was the simple removal of the pathological element (a sort of *restitutio ad integrum*), the current framework is much more complicated. [16] The medicalization extended to every human activity and the technological possibilities suggest a different idea of 'the role of the doctor'. Therapy is no longer just an activity aimed at restoring a lost condition, but it is also the activity that tries to enhance the human being. In this framework, health is not just the condition in which we are, or our bodily integrity, the bio-statistic normality, "a state of complete physical, mental and social well-being", or something else. Health is also a sort of potential goal, a future condition that legitimizes the use of enhancement practices. [17]

Already in the e-health models that are currently being tested, the connection to a network allows a continuous update to monitor one's health. The use of big

comment of FP Grad, 'The preamble of the constitution of the World Health Organization' (2002) 80 Bulletin of WHO 981.

[14] A common definition of health in Italian courts is "the condition of the average human being", M. Rossetti, *Il danno alla salute* (CEDAM 2017) 126; on the biostatistical theory ant its critique B.M. Kious, 'Boorse's Theory of Disease:(Why) Do Values Matter?' (2018) 43(4) J Med Phil 421; *pro* P.H. Schwartz, 'Reframing the disease debate and defending the biostatistical theory' (2014) 39(6) J Med Phil 572; C Boorse, 'A Second Rebuttal on Health' (2014) 39 J Med Phil 683.

[15] On the relative meaning, against the biostatistical theory, D.J. Guerrero, 'On a naturalist theory of health: a critique' (2010) 41(3) Stud Hist Science 272; recently, again, A. Broadbent, *Philosophy of Medicine* (Oxford University Press 2019).

[16] E.D. Pellegrino 'Biotechnology, Human Enhancement, and the Ends of Medicine' (2004) 10(4) The Center for Bioethics and Human Dignity 1.

[17] On the concept of enhancement, JC Heilinger, *Anthropologie und Ethik des Enhancements* (Walter de Gruyter 2010), 59.

data, risk assessment operations and 'patient-user' profiling could play a decisive role both in disease prevention and in strengthening individual health. In this context, then, the concepts of health and therapy could be transfigured entirely, given that they are already making a partial but significant twist. [18] Furthermore, the historical nature and relativity of the concept of health has already been affirmed on the level of the philosophy of medicine, with ample proof of the groundlessness of many defining approaches of the last century. [19] The naive visions of health as a condition of 'normality' have been widely criticized.

As for the law, courts and legal doctrines are still very much linked to traditional notions of health, but the new technology could overwhelm the current legal framework. A humanity that is always connected with health institutions, also thanks to the Internet of Things, could live in a continuous sharing of the healthcare information, with the consequence of living in a dimension that is always 'pathological' and, therefore, always in need of constant diagnosis and therapy. In such a landscape, diagnosis and treatment would not only be sporadic activities; several technological devices could continuously manage our health, considering consumption, activities, displacements, analysis results, genetic tests, etc. These are not science-fiction considerations if we observe that the leading players in the digital sector, both public and private, are planning more and more investments in artificial intelligence in the health sector. [20] A recent case, finally, confirms this assumption and more than one clue leads us to imagine an upcoming disruptive innovation even in this sector. [21]

2. Confidentiality and data sharing in new healthcare models

In the current medical approach and the future, health treatment involves a necessary activity on the patient's data. Indeed, a part of the health treatment coincides with the processing of health data. If, however, this statement seems to have always characterized the doctor-patient relationship, since therapy necessarily involves the

[18] P.D. Scripko, 'Enhancement's place in medicine' (2010) 36 J Med Ethics 293; from a point of view of neuroscience and neuroethics, B Gordijn, 'Neuroenhancement', in J Clausen, N Levy (eds.), *Handbook of Neuroethics* (Springer 2015) 1169.

[19] A. Broadbent, *Philosophy of Medicine* (Oxford University Press 2018) Part. A Chapt. 4.

[20] On the development of e-health, WJM Stevens et al., 'eHealth Apps Replacing or Complementing Health Care Contacts: Scoping Review on Adverse Effects' (2019) 21(3) J Med Int Res e10736; also P. Guarda '"Ok Google, am I sick?": artificial intelligence, e-health, and data protection regulation' (2019) 1 BioLaw Journal 359.

[21] D. Blumenthal, 'Why Google's Move into Patient Information Is a Big Deal' (2019) Harv Bus Rev 26.11.2019.

management of data, in the digital environment, a different need for sharing the personal information flow is required. The issue entails, first, that the patient's confidentiality cannot be sufficiently protected only by professional secrecy; an obligation that modernity has borrowed from the Hippocratic tradition.[22]

However, the actual doctor-patient relationship imposes a more complex reflection. First, this relationship is realized, with a significant frequency, within complex organizational structures, both public and private. Also, as a result, the therapeutic activity is not carried out entirely by a single healthcare professional, but with the complicity of different actors. In this minimum and partly discounted coordinates, the need to record patient information and the problem of a regulated sharing could arise. Already in this perspective, the patient's confidentiality cannot be protected only by the professional secret, but it requires a specific health data protection regulation, to which every privacy law, by now traditionally, pays special attention.[23]

In the e-health systems the data processing plays a different and wider role. The quantitative increase of records and the computational possibilities change the landscape. The recording of data, in fact, does not only reflect the organizational purposes of the structure but directly affects the therapy, also because of the appearance of artificial intelligence as a possible 'third actor' of the doctor-patient relationship.[24] In an e-health system, the data of the individual can be

[22] About the Hippocratic oath, D Cantor (ed.), *Reinventing Hippocrates* (Routledge 2016); on its relevance in new world H. Askitopoulou, A.N. Vgontzas, 'The Relevance of the Hippocratic Oath to the Ethical and Moral Values of Contemporary Medicine. Part II: Interpretation of the Hippocratic Oath Today's Perspective', (2018) 27 Eur Spine J 1491.

[23] The statement that health data are a special category is common to the previous systems, specially to the ones based on the Directive 95/46/EC on the protection of individuals with regard to the processing of personal data, in which, according to art. 8, «Member States shall prohibit […] the processing of data concerning health or sex life», but this prohibition should «not apply where processing of the data is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services, and where those data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy»; in the GDPR, art. 9 states that «the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation shall be prohibited», but this paragraph shall not apply in some other specific case, such as when «processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices», when there's a specific consent of the data subject, or other cases generally attributable to reasons of public interest.

[24] On the idea of Artificial Intelligence as a 'third actor' in medicine, C. Brall, P. Schröder-Bäck, E. Maeckelberghe, 'Ethical aspects of digital health from a justice point of view' (2019) 29(3) Eur J Pub Health 18.

used, together with those of others, for the acquisition of new knowledge. The model, however, has a direct impact on individual health, as in the case of personalized medicine, giving back some recommendations to the individual, following statistically oriented risk assessments. [25]

Furthermore, an artificial intelligence system can provide support in diagnostic or intervention techniques. The risks of error are significant, and the management of the possible consequences involves issues of responsibility, which are also recorded in other areas of new technologies, from robotics to artificial intelligence in general. [26] As a consequence of this statement, the new Regulation doesn't require anymore, in any case, the consent of the subject and the prior approval of Authorities, as in the previous system. [27]

In fact, according to GDPR, the processing of health data for medical purposes has an autonomous basis of lawfulness, an alternative to the consent. In other words, special categories of data can be processed, including those concerning health, or according to the consent of the data subject (as in the case of medical apps), or according to other specific reasons, as when the processing is necessary for a medical treatment (again, art. 9, letter h). [28] In the case of therapy, for example, there is no more need for the consent to the processing, because the activity requires the processing. In any case, except some 'involuntary treatment' (medical treatment undertaken without the consent of the person), the doctor-patient relationship is based on the informed consent. For this reason, the consent to data processing is somehow involved in the bigger consent to therapy, in the general framework of the relation doctor-patient.

That is why, the obligation of confidentiality of the doctor and, more generally, of the health professional and her/his collaborators gains in today's context a greater gravity than in the past. The protection of confidentiality in the ethical framework is no longer resolved only in an obligation 'not to do', in the prohibi-

---

[25] On the possibility to use big data and profiling to a risk assessment in e-health, L Lella et al., 'Predictive AI Models for the Personalized Medicine' (2019) Biostec Healthinf 199; in the psychiatric field, L. Barrigon et al., 'Precision medicine and suicide: an opportunity for digital health. Reports' (2019) 21(12) Curr Psychiatry Rep 131.

[26] On these issues, C. Allen, I Smit, W Wallach, 'Artificial Morality: Top–down, Bottom–up, and Hybrid Approaches (2005) 7(3) Ethics Inf Tech 149; or D.G. Johnson, 'Technology with No Human Responsibility?' (2015) 127 J Bus Ethics 707.

[27] On the effectiveness of consent, also in a perspective of interaction design, see L. Gatt, R. Montanari, I.A. Caggiano, 'Consenso al trattamento dei dati personali e analisi giuridico-comportamentale. Spunti di riflessione sull'effettività della tutela dei dati personali' (2017) 2 Pol dir 337.

[28] The different system between medical apps and usual doctor-patient relationship is confirmed by the Italian Authority, Garante Privacy, *Chiarimenti sull'applicazione della disciplina per il trattamento dei dati relativi alla salute in ambito sanitario - 7 marzo 2019*, n. 55 /2019.

tion of disclosure of patient information. That means that the protection of confidentiality takes place, also on a deontological level, in compliance with the principles and obligations set in the new Regulation. Therefore, the deontological horizon of the healthcare professional is no longer described just by reference to professional secrecy, but it is achieved primarily through active and complex conduct. Because of this, in the new Regulation, the codes of conduct are more important than in the past, thus entrusting the actors of health data processing with a guaranteed role. [29] The GDPR recognize a diffused power, which is implemented within the framework of private self-regulation and soft law. [30]

3. A human-centred technology? The *naïve* approach to the balance of fundamental rights

It is now necessary to attend the plan of possible solutions for the regulation of e-health, considering the change of the concepts of privacy and health in the new framework. This specific question is related to two general issues: the regulation of artificial intelligence and the impact of new technologies on the categories used in the bio-legal field. Both issues can be treated with a general and common theoretical approach, because there is a common background, in terms of risks for fundamental rights and use of soft law instruments.

In the first analysis, the theme of transparency is central. But behind the call for transparency, various conflicts are concealed, for the most part unsolved: protection of software ownership and the right to be known by the interested; patient confidentiality and ambition to make use of the progress determined by information sharing, etc. [31] In this context, it is only useful to recall the progressive erosion of the principle of pseudo-anonymisation in scientific research. [32]

---

[29] N. Miniscalco, 'Le regole deontologiche nella disciplina della privacy', in S. Scagliarini (ed.) *Il "nuovo" codice in materia di protezione dei dati personali* (Giappichelli 2019) 39.

[30] On soft law instruments entrusted by GDPR, L. Floridi, 'Soft Ethics: Its Application to the General Data Protection Regulation and Its Dual Advantage' (2018) 31(2) Phil & Tech 163–167; or also B McCall, 'What does the GDPR mean for the medical community' (2018) 391 Lancet 1249.

[31] E. Vayena et al., 'Policy implications of big data in the health sector' (2018) 96 Bulletin WHO 66; T. Wykes, S. Schueller, 'Why Reviewing Apps Is Not Enough: Transparency for Trust (T4T) Principles of Responsible Health App Marketplaces' (2019) 21(5) J Med Int Res e12390

[32] H.T. Tavani, F.S. Grodzinsky, 'Responding to Some Challenges Posed by the Re-identification of Anonymized Personal Data' (2019) *Computer Ethics-Philosophical Enquiry (CEPE) Proceedings* 2.

The pseudo-anonymisation is a technique contrary to the profiling mechanisms of e-health models and in any case, useless due to the significant probability of re-identification of the anonymized data. This results in a paradoxical effect: a person's private life becomes transparent, while the 'machine' that investigates it and orients meaningful choices, be they public or private, stays unknowable. [33]

This occurs both because of the individual's inability to understand the complexity of artificial intelligence software, and because of the objective 'unfathomability of the algorithm's reasons', which in the case of deep learning, are lost in overlapping data classification levels. [34]

The transparency of the software and the completeness of information aim to perform, then, an instrumental function for the responsibility and the control of the activities. Nonetheless, the framework of the Regulation is so wide and undefined that isn't that simple to understand the direct application. The main consequence could consist of the attribution of normative value to practices or standards. [35] In the case of private medical research, this is a very risky regulatory hypothesis, even for intuitive reasons.

In the same way, the appeal to the quality of technology, to the state of the art as a criterion for evaluating the protections, must be considered problematic. Art. 32 GDPR states that the appropriate measures are adopted, "taking into account the state of the art and the costs of implementation and the nature, scope, context and purpose of processing". In this case, the presumption of a too high technological standard would have prevented the access of new and small players to the digital market. Thus, the need for protection of competition and the creation of a stronger European digital market led to a more flexible solution, as opposed to the concept of standards. The expected quality is commensurate case by case. This certainly allows and greater sensitivity to competition and greater flexibility. However, the real risk is that the 'state of the art' could be a moveable standard and, therefore, too often the opposite of a standard rule.

Finally, in several documentations of ethics and law of artificial intelligence, there is great attention to the risk of discriminatory effects of the algorithms and to the potential impact on fundamental rights. [36] At this level we find the es-

[33] On the relevance of the 'knowability of the aglorithm', see G De Minico, 'Big Data e la debole resistenza delle categorie giuridiche. Privacy e lex mercatoria' (2019) 1 Dir Pubbl 89.

[34] M. Ananny, K Crawford 'Seeing without knowing: Limitations of the transparency ideal and its application to algorithmic accountability' (2018) 20(3) New media & Soc 973.

[35] B. Toebes, 'Global health law: defining the field', in GL Burci, Id. (eds.), *Research Handbook on Global Health Law* (Edward Elgar Publishing 2018) 2.

[36] On this topic T.B. Gillis, J.L. Spiess, 'Big Data and Discrimination' (2019) 86(2) University Chicago Law Rev 459; in medical field WN Price, IG Cohen, 'Privacy in the age of medical big data' (2019) 25(1) Nature med 37; in this review, A. Fabrocini, 'Artificial Intelligence, Data

sence of every appeal to the construction of a human-centred technology: in this sense, the principle of equality (or equal protection clause), the protection of fundamental rights and a variable set of philosophical and juridical values are evoked. However, these appeals seem to outline a sort of coexistence of fundamental rights, almost a harmony that excludes potential conflicts, sometimes with a generic reference to the concept of dignity.[37] It is true, in the opposite, that both equality and fundamental rights involve frequent conflicts and necessary operations of balance.[38] This balancing operation is usually made by the democratic decision of a parliament, or at least, by supreme or constitutional courts. It could be too hard to expect all these sensitivities in a software programmer and some of these appeals refers to a naïve approach to the problem, if not a sort of 'do-gooder method'.

Legislative power often appears unsuitable for the regulation of technological progress, from many points of view and first because of its slowness.[39] For other reasons, it is not possible to rely only on the power of the courts, that too often enforces practices of the privates. Besides, we could underline the role of public para-jurisdictional bodies, such as independent authorities, which have several regulatory instruments.[40] Even authorities need to recover elsewhere the

---

Protection and Privacy: European Parliament Resolution of 12 February 2019 on "A comprehensive European industrial policy on artificial intelligence and robotics' (2019) EJPLT News 30.04.2019.

[37] For a view of this concept in our legal doctrine, see also A. Pirozzoli, *La dignità dell'uomo. Geometrie costituzionali* (ESI, 2012) 184.

[38] See also O. Pollicino, O. Soldatov, 'Judicial Balancing of Human Rights Online', in M. Susi (ed.), *Routledge Handbook on Digital Society, Human Rights and Law* (Routledge 2019); in medical research, H.B. Bentzen, N Høstmælingen, 'Balancing Protection and Free Movement of Personal Data: the New European Union General Data Protection Regulation' (2019) 170(5) Ann Int Med 335; for the balance in Italian doctrine, see G. Zagrebelsky, *Il diritto mite. Leggi diritti giustizia* (Einaudi 1992), and R Bin, *Diritti e argomenti: il bilanciamento degli interessi nella giurisprudenza costituzional* (Giuffrè 1992); see also F. Modugno, *I nuovi diritti nella giurisprudenza costituzionale* (Giappichelli 1995) 94; or Id., 'Interpretazione per valori e interpretazione costituzionale', in G. Azzariti (ed.), *Interpretazione costituzionale* (Giappichelli 2007) 51, *contra*, in the same book, A Pace, 'Interpretazione costituzionale e interpretazione per valori', 83; shortly G. Pino, 'Conflitto e bilanciamento tra diritti fondamentali. Una mappa dei problemi' (2006) 1 Et & Pol 1; on the legal concept of 'value' in continental legal culture, see A. Longo, *I valori costituzionali come categoria dogmatica*, (Jovene 2007) 110; recently and focused on law and new technologies, see G. Resta, *Diritti fondamentali e diritto privato nel contesto digitale*, in F Caggia, Id. (eds.), *I diritti fondamentali in Europa e il diritto privato* (Roma TRE-Press 2019) 117.

[39] S. Sileoni, *Autori delle proprie regole I codici di condotta per il trattamento dei dati personali e il sistema delle fonti* (CEDAM 2011); A. Iannuzzi, *Il diritto capovolto* (Editoriale Scientifica) 2018.

[40] C. Etteldorf, 'Data Protection Authorities Try to Fill the Gap between GDPR and e-Privacy Rules' (2018) 4 Eur Data Prot Law Rev 235.

rules to apply; but they can't rely just on legislation, hard law instruments or, again, on private standards.

Temporary conclusions

It is clear that the complexity and importance of this set of problems cannot be only managed by the self-regulation of private individuals, not because they pursue dark or illegal interests, but because the privately-owned enterprises cannot take on the framework of values, principles and rights we are dealing with. The appeal to the role of the public actors seems to be appropriate in the regulation of this sector.

There are currently no definitive solutions. Therefore, the scientific and lawyer communities are called to a particular commitment: to define a new *nomos* of the digital space. [41] They should gain a specific role in the complex geometry of soft law instruments and try to translate the temporary results of the scientific research in concrete patterns that can be used by the community of professionals and programmers. Specific patterns could mean documents, practical management models, governance models for companies or deliverables as a result of collective projects. [42] In the case of health, medicine, medical research and the protection of health data, this hypothesis requires the collaboration of scientists coming from different fields, from computer science to law, from bioethics to medicine.

[41] The concept of nomos also could refer to the approach of A von Bogdandy, S Hinghofer-Szalkay, 'European Public Law – Lessons from the Concept's Past', in Id., S. Cassese, P.M. Huber (eds.), *The Administrative State* (Oxford University Press 2017) 30; see also A. von Bogdandy, 'Il diritto amministrativo nello spazio giuridico europeo: cosa cambia e cosa rimane', in Id., P. Schiera, S. Cassese, *Lo Stato e il suo diritto* (Il Mulino 2013) 97.

[42] I. Carr et al., *Ethical design. At the Interface of Ethics for Big Data and the European Union's General Data Protection Regulation: deliverable D13. 2* (EU 2018).