

De uma organização resiliente a um bom relacionamento entre regras e tecnologias: governando o progresso científico em um moderno sistema de saúde

Between rules and technologies: ruling scientific progress in a modern healthcare system

Regulación del progreso científico en un sistema de salud moderno: desde una organización resistente a una buena relación entre reglas y tecnologías

Reglementer les progres scientifiques dans un systeme de sante moderne: organisation resiliente et bonne relation entre regles et technologies

Monica De Angelis¹

RESUMO: Este artigo teoriza como as regras podem responder a futuras inovações e mudanças já em curso no setor da saúde. Tecnologias, digitalização e inovação são um desafio para todo legislador em todo o mundo: o amplo uso da robótica, por exemplo, molda o setor da saúde mais rapidamente

¹ Professore associato in Diritto amministrativo, Università Politecnica delle Marche, Italia. Email: m.deangelis@staff.univpm.it

do que as regras poderiam dar uma resposta adequada. Além disso, elementos distintos da era tecnológica atual desafiam as categorias jurídicas tradicionais e levantam novas preocupações regulatórias: especificamente, o progresso científico dos cuidados de saúde levanta questões complexas que não são fáceis de responder. As lacunas normativas não podem ser preenchidas de alguma forma esticando ou reformulando as regras legais existentes, mas sim exigindo um papel proativo do direito público. Este artigo, referindo-se a estudos de caso, sublinha as discrepâncias existentes entre o momento do progresso científico e o tempo dos legisladores e da administração. Este artigo também aponta a dificuldade consequente na criação de um quadro normativo, que deve ser por vezes apenas esboçado e, por vezes, o mais detalhado possível.

Palavras chave: Codificação. progresso científico. direitos do paciente. resiliência na administração pública.

ABSTRACT: This paper theorizes how rules might respond to future innovation and changes already underway in the health sector. Technologies, digitalization and innovation are a challenge for every legislator worldwide: the wide use of robotics, for instance, shapes the health sector faster than the rules could give an adequate response. Moreover, distinctive elements of the current technological era challenge traditional legal categories and raise new regulatory concerns: specifically, health care scientific progress raises complex questions not easy to give an answer to. Normative gaps cannot be filled by somehow stretching or reshaping the existing legal rules, but rather call for a proactive role of public law. This article, referring to case studies, underlines the discrepancies existing between the timing of scientific progress and the timing of law-makers and the administration. This article further points out the consequent difficulty in creating a normative framework, which should be at times only sketched and at times as detailed as possible.

Key words: Codification. scientific progress. patients' rights. resilience in Public Administration.

RESUMEN: estas páginas teorizan cómo las reglas podrían responder a la innovación futura y los cambios que ya están en marcha en el sector de la salud. Las tecnologías, la digitalización y la innovación son un desafío para todos los legisladores: el uso generalizado de la robótica, por ejemplo, está dando forma al sector de la salud más rápido de lo que permiten las reglas. Además, los elementos distintivos de la tecnología actual desafiaron las categorías legales tradicionales y plantearon nuevas preocupaciones regulatorias: atención de la salud, avances científicos, etc. plantear preguntas complejas que son difíciles de responder. Las brechas normativas no se pueden abordar de manera satisfactoria ampliando o modificando las normas legales existentes, sino utilizando un papel proactivo en el derecho público. Este artículo, en referencia a los estudios de caso, subraya las discrepancias existentes entre el momento del progreso científico y el tiempo de los legisladores y la administración. Este artículo también destaca la dificultad resultante de la creación de un marco normativo, que a veces debe ser solo esbozado y en ocasiones lo más detallado posible.

Palabras clave: Codificación. progreso científico. derechos de los pacientes. resiliencia en las administraciones públicas.

RESUME: Cet article théorise la manière dont les règles pourraient répondre aux innovations futures et aux changements déjà en cours dans le secteur de la santé. Les technologies, la numérisation et l'innovation représentent un défi pour chaque législateur: l'utilisation généralisée de la robotique, par exemple, façonne le secteur de la santé plus rapidement que ne le permettent les règles. En outre, des éléments distinctifs de la technologie actuelle remettraient en question les catégories juridiques traditionnelles et soulevaient de nouvelles préoccupations en matière de réglementation: soins de santé, progrès scientifiques, etc. soulèvent des questions complexes, auxquelles il est difficile de répondre. Les lacunes normatives ne peuvent être comblées de manière satisfaisante en étirant ou en remodelant les règles juridiques existantes, mais en faisant plutôt appel à un rôle proactif du droit public. Cet article, faisant référence à des études de cas, souligne les divergences existant entre le moment choisi pour les progrès scientifiques et le moment choisi par les législateurs et l'administration. Cet article souligne en outre la difficulté qui en résulte pour la création d'un cadre normatif, qui devrait parfois être seulement esquissé et parfois aussi détaillé que possible.

Mots clés: Codification. progrès scientifiques. droits des patients. résilience dans l'administration publique.

INTRODUCTION: RULES IN STRICTER AND SLIGHTLY HINTED FRAMES ¹

In an age where technology and innovation are pillars of society, analyzing the juridical issues (such as constitutional principles, intersecting rules, administrative decisions, bureaucratic design, etc.) arise when scientific discoveries are inserted in the healthcare system is ever more complex: this because the scientific progress, nourished by new technologies (this is the reason why is it possible to talk about *technological progress*), requires answers often difficult to be identified. Primarily because the legal dimension of the issues produced by technologies sets off many consequences in a number of areas: for instance, in medical practice, in the patient's legal field, in health policies. Furthermore, either the answers generated by laws, either application practices should in addition reflect the different orientations proposed and showed by various legal cultures.

The considerations related in this theme are many, in the following pages there will be a focus only some of them. The principal aim of this paper is to underline that technology and science (in general) must be regulated (*ubiscientiaibiura*)²but if there is a need for regulation, it is necessary for this regulation to operate according to the specific characteristic of the sector, of the service, of the context, of the particularities of the right under review. We also need to consider that the introduction of rules regarding scientific progress is not simple due to the transnationality. So, there will be situations which a stricter frame of regulation will be needed for and other cases which slightly hinted frame will be needed for.

Looking at several specific Italian cases it is possible to easily note that, in regards to certain issues the law does not provide a univocal answer sometimes referring to indeterminate legal

principles, other times referring to ethical rules, some other times referring to detailed regulations: an example might be the regulation of medically assisted fertilization or compulsory treatment³.

Even if the codification of the new phenomena doesn't encounter particular ethical or juridical obstacles, the scientific progress and technological development need attention from at least two corners: new drafting methodologies by traditional standards (these new methodologies provide for different paths for the construction of upstream and downstream rules and new ways of training the rule makers); and the development a resilient administrative organization within the healthcare system that is able to resist, to absorb, to adapt and recover in an efficient and timely manner from the effects of new regulations. This may need the ongoing protection and recovery of its structures and essential functions⁴.

Therefore, new technologies require a new connection between rules and healthcare system and the parties who apply those rules: for example, technologies impose a different way of thinking about the protection of patients rights' targeted at their specific needs; technologies affect how traditional legal principles and arrangements are applied: for example, proportionality, privacy, responsibility and justiciability. Moreover, administrative organization, health care structures and planning services must be modulated and adapted to reconcile new innovations and established practice.

Basically, this paper wishes to demonstrate that is not simply a matter of creating and imposing rules on the healthcare systems run over by the scientific progress. In these instances it would appear to be more convenient to apply perspective principles rather than static rules and have a comprehensive vision of the healthcare organization in the hands of the actors who will implement those principles (so called *anticipatory governance*).

In an evolving system as healthcare is, it is necessary to face a high complexity that comes not only from the intrinsic characteristics of the different actors responding to the needs of cares and health care protection (public, private accredited and private entities), but also by needs posed by institutional and technical sub-system.

Faced with the constant search of appropriateness in the delivery of services, health care providers will have to confront the legislative "hetero imposition" and at the same time they have to demonstrate ability to respond both to the objectives set by the essentially public healthcare's nature, and to the influences exerted by the scientific community. This needs to occur within a framework of shared values and principles absorbed by the health professional groups and organizations. The health system must prove to be resilient and manage the rules through adaptive modalities (so called management of rules).

Technology itself (we refer in particular to ICT) helps in the pursuit of this intent: the systems are increasingly digitalized and processes and decisions also follow this rhythm. In the last years

communication or contact between institutions and citizens is increasingly done via technologies. In this way technologies make the relationship between citizens and institutions (that is – in our case - the relationship between patients and the healthcare providers) easier and simpler: e.g. the digitization of procedures and medical records management or the transmission of health expenditure data for tax purposes.

In fact, technology enhances communication, having a multiplier effect on relationships: the intelligent use of continuous stream of data and information enables patients to interact with the services' providers in order to improve performance (dissemination of good practices, movement of experimental and clinical research, cross-border healthcare).

The players of the healthcare system should move beyond a traditional administrative use of digital technologies (that is doing quickly what previously was done in analogic), because the aim is not to create a “digital patient of a smart healthcare system”, but to use technology (and not only ICT) to reorganize services to ensure its use according to strategies relating to appropriateness and satisfaction.

Technologies applied to the healthcare sector (and not only to healthcare), should be useful in the care of citizens' interests, and should be closely related to scientific progress as well as to the improvement of the social system as a whole. This relationship should be obvious as technologies impose technical issues. These issues rise, in fact, arise even in political arena: for instance. the choice to legislate or not legislate on topics such as the neutrality of Internet, or the responsibility of the health professional in the use of cybernetics. In other words, when the legislator can choose whether to legislate or not, he's making a political choice, not a technical one. Moreover, when the rule maker chooses to intervene it is assumed that it is in order to protect public interests: the choice involves not only the *an* (if we should introduce rules) but also the *quid* (what rules) and *quomodo* (in which way we can regulate).

It is not easy to determine the way to legislate and when legislator should intervene on situations invested by new technologies. In any case, the legislator must take into account the political context where to act, if the purpose is to have an efficient and effective result.

Preferably technological innovation should have rules after its effects have been unfolded: this is because if we want useful rules, we have to observe what kind of consequences are being produced by the technologies.

The introduction of mandatory rules should be applied at a later stage; this is because binding rules may cause more difficulties with the innovations. In order to guide and influence, the choice to set some rules before the complete effects are known, should be made as general guidelines, Definitions and details should be left to a later stage, keeping in mind that any rule should respect fundamental rights and have less adverse effect as possible on the legal guarantees of interested

parties.

Otherwise, despite the usefulness of technology, the decision to rule it may not be helpful: hence the opportunity to consider a soft law approach (we ask for not only useful technologies but also useful rules on technology). This approach would appear to be better because it better respects the specificity of the healthcare system in an era whose response time are different from the traditional ones. This is ever more important given that “we are very quickly going to what was imagined in the movie *Transcendence*, where tech machines are able to instantly build parts of the body, eliminate distortions, give back life”⁵.

This kind of situation poses legitimate dilemmas: who is responsible if a part of the robot is causing damage? What about individual freedoms when some decisions can be made by a machine? What is the limit of human dignity, if machines give impulses to the vital organs and give signals about life’s moments to be shared with others?). These dilemmas will not constitute, however, a strong counterweight to the advance of “technologies supporting healthcare”.

Finally, do not forget that we can demand elasticity to regulations in order to maximize adaptation the rapidity of scientific progress and - at the same time - provide reasonable protection to the rights of all persons involved; we need also to respect /we should respect the autonomy and the freedom of research, by the legislator and or all public authorities. In any case, these are all open issues far from having a quick and easy solutions or response.

THE WAY TO RULE TECHNOLOGIES IN HEALTHCARE AND RULES’ TECHNIQUE (THE TECHNIQUE OF BUILDING RULES): BEYOND THE PLAY OF WORDS

The way to rule technologies in health care is different from the rules’ technique related to health care, despite being very different phenomena are often inextricably linked: just think about the relationship between the development of good rules and the quality (meaning adequacy) of response in terms of rules for the introduction of new technologies in health care. In other words, if it is fundamental for the governance of a system to apply advanced rules’ technique, it is equally important to rule the use of technology: as well as economic growth and how markets are regulated, also in the era of technological and scientific progress, the implementation of the right of health depends on the regulatory framework and how these rules are built and applied⁶.

As it has been rightly pointed out, however, in general, science involves both the legislator “who is asked to produce rules aiming to respect the scientific autonomy, guaranteeing the fundamental rights of the human being, [and the administrative bodies as well as] the judges (at constitutional and local level), which [often] intervene [...] due to laws which do not respect the scientific autonomy or even to fill legislative gaps” and or to give substance to aspects that rules left undetermined. Highlighted the close link between the way to rule technologies and the rules’ technique in healthcare, it is important to emphasize the different effects these have on the right to health, on its implementation and its protection. In fact the impact on the right to health by general

rules and undefined legal concepts, rather than detailed rules with high “technical content” it is very different.

And more: one way is to lay down rules on the persons entitled to have a given benefit or rights, the other is to codify with specific details the procedures for the exercise of the benefits or rights.

In both these cases you need to decide whether to rule and what to rule, or if the focus should be on how to rule. In other words, when you move to regulate the technology and scientific progress in health, not only do all the classic problems of decision-making and legislative powers are highlighted but also others problems come out or at least some profiles get complicated.

Just consider the issue of medically assisted procreation (MAP) whose sublimation is in the law n. 40 of 2004: its rules involve the general profiles, the planning of health services, the research and the type of treatment from a subjective and objective point of view, the budget decisions, the discretion of the health authorities concerned as well as the legal protection of the right and so on. The high level of technicality related to this subject resulted in the well known and complicated events that have affected the construction of the legal framework in Italy, its application and finally in its almost total demolition at least in some parts⁷: this legislator, in fact, has expressed both in an anachronistic way when compared to the possibilities offered by scientific progress in this field and in the corresponding expectations of the patients concerned. Besides, the same regulatory framework has resulted in several points of damage to the constitutionally protected right to health. Particularly where there are more detailed rules its application has weighted heavily on the right to health of those concerned, even overstressing judges making rulings on the effects those technical rules were causing.

Overall, therefore, legislative technique used to regulate this subject (social decontextualization, principles and objectives of law not clearly defined and therefore conflicting, contradictions with respect to technical and scientific issues, and so on) has been unsuccessful and consequently the quality of the law ultimately has turned out to be limited.

With respect to the protection of the rights it is not only relevant the quality of rules’ technique.

Another important issue in this area is connected to the timing in which to intervene and apply with regulations. Not only, *how* to regulate (more or less detailed rules, references to international standards, etc.), but also *when* to rule is essential.

Facing the problem of regulating is of crucial importance every time biotechnology advances with a new product, the medical-pharmacological trials proceeds, or every time there are improvements in robotics. In fact, facing the progress of science and technology, e.g. before the development of robotics, which is ongoing, it is hard to dismiss the feeling that the existing laws are inadequate and insufficient to regulate in all area of its implications and or the interaction between men and machines.

Take the case in which artificial intelligence reports the enhancement of human capacity not by a surgery that modifies the body, but by “the activation of the man-machine continuum made possible by special devices - - such as synthesizers voice or brain Computer Interfaces - it – which can create interconnections between a “human brain” and electronic “brain”, in order to allow communication with conscious patients but unable to express themselves through speech, gestures or writing”⁸. One can wonder if the associated rules, regulations of all the associated issues (e.g. accountability for actions, etc.) should be made before or after knowing the real potential of the application and the effects of new technologies. There is still another issue.

Let’s assume that in the near future the so called “personal robots”⁹ will be able to perform actions with autonomy and cognitive capacity – that is actions that are not set in memory. These would be daughters of decisions taken by the machine according to the processing of the information acquire and as a result of these actions there is injury to property or persons. In this case as elsewhere, “there is a need to provide protection of the rights of citizens as consumers struggling with a particularly sophisticated technological product. In this case it is true that the already existing rules and regulations relating to the machines object can be applied, but it is unclear as to whether these rules can be applied to cover all eventualities”¹⁰.

However, with this rationale, the aim is not to place limits to the scientific progress but rather to support and to concretely develop the rules once the effects of new technology are produced and known and are not covered by existing rules. This would avoid redundancies or duplications. Initially legislation needs to be flexible and only when the results of technological innovations are stabilized, would it be useful to apply binding regulatory systems.

The aim would be to have fewer rules but that the rules would be of a better quality. It is impossible to plan out the whole of life given that ruling all its aspects could at times negatively impact on a patient and or his or her rights. After all, the question can be asked, it is always necessary to establish legal rules and rulings? Laws rigidity cannot be an obstacle to the exercise of ones’ rights?

The rules imposed from the top, by the legislator and by administrative acts are not too invasive in some cases when compared to the specificity of clinical and organizational situations often very different from each other?

Is it better that “the right to health in the age of technology” be a right built on general regulatory provisions, which leaving broader operating spaces to specialized administrations, professionals and judges? The discipline should perhaps be eminently jurisprudential or should be persuasive¹¹? Are the remedies available via judges and judgment ahead of the application of technical standards applied to situations where the technique and technology have a leading role?

The answers to questions like these are crucial in order to define the frame of reference for action

to juxtapose technological progress and the right to health.

TECHNICAL REGULATION AND RESILIENT ADAPTATION: FROM SOFT LAW TO PATIENTS' PARTICIPATION. SOME NOTES

If it is almost indisputable that the right to health appears to be conditioned by the legislative technique and the presence of technical requirements, it is also interesting to ask whether and how the gradual increase in legislation affects the protection of patients' rights. This question deserves significant attention but is however beyond the scope of this paper. Therefore we will make some general comments. The success and the increasing use of technology - along with historical, political, economic and social factors - has helped to create conditions for the development of less traditional formulas and technical regulations.

It is mostly new regulatory instruments (soft law) that seem to better adapt to the complexity of modern society and to be more appropriate to give answers to the current problems associated with globalization and the interdependence of markets, institutions and the collectivities. In other words, where it is difficult to legislate, it may be more appropriate to rule with soft law rather than no rules at all. Rather still waiting for the effects of new technologies to occur so that we can proceed to creating and or setting possible binding rules¹².

In this vein of rulemaking can be ascribed the acceptance of charters of users' rights e.g. Chart of Internet rights or new ethics rules and or rules on ethical behavior to be included for the purpose of evolution of more adaptive realities compared to traditional ones.

In order to provide a set of conditions aimed at the introduction of new general laws and new more adaptive organizational framework may include ethics, diligence, behavior of participants to modulate facing technologies (particularly for health professionals).

Still anchored in past methodologies, for example, is the recent renewal of the code of medical ethics strongly emphasizing that the diagnostic and therapeutic skills are professional and underlining the mandatory nature of personal contribution.

The amended code, in fact, exudes fear of the technology. It is true that the professional making use of telematics systems cannot replace the examination and the direct relationship with the patient with a predominantly virtual relationship. It is equally true that technology - and more generally science, are improving the ability to diagnose and treat diseases for the benefit of patients. Therefore, there would be a moral obligation to know and take full advantage of all that technology (not only IIT) that leads to positive and scientifically valid outcomes, both in medicine as in the organization of healthcare.

The soft approach to regulation, makes it possible to maximize the adaption and implementation of the broad scope of constitutional principles of guaranteed rights. This approach also makes it

possible to better govern and manage the impact of technological development. This also allows all parties become more resilient in the adaptation of new technologies within the health care system. This would magnify the patients' active role in the modification, construction and evolution of new rules and guidelines.

The patients acquisition of a technical role merges well with the development and spread of electronic and high care techniques, wearable technology or the care pathways related to so called family learning¹³. Example of this might be continuous monitoring systems at the patient's distance (including the robotic assistance) and feedback systems¹⁴ driven by the same patient.

“Education to new technologies” is therefore a key element to build awareness of the benefits and risks that technological and scientific progress entails because they affect the entire relationship between health system and patient. This is from the protection rights to health to the doctor-patient relationship, from the access of treatment to the territoriality of the delivery of services. Tools such as the health card, the electronic medical records, booking services and drugs and reporting online, cloud computing, social media and mobile technology can really change the paradigms of the responses from the healthcare system to the needs of its users. Thanks also to a general administrative and operational framework directed to the logic of open government, to real simplification of procedures, to the “network management”¹⁵ and then to sharing decisions and participation. In other words, the contribution of scientific and technological progress should move up non-traditional schemes and non-traditional paths: and this is as true for the rule-making and for the governance and healthcare practice.

In fact, ever-increasing massive use of eHealth and eGovernment gives good prospects for improvement, especially from the side of the rationalization of resources and the recognition of citizens' needs. The services related to this area in the health sector are already quite popular, but there are very high growth margins: for example, the application of friendly innovative media - such as forums, blogs, chat - for purposes such as the reduction of waiting lists and user satisfaction still have a large potential for development.

THE TECHNICIANS IN ACTION: THE ADMINISTRATION AND THE COURTS

The regulation of technology and rules' techniques lead us to reflect on the actors who build and apply the rules. In a society governed by complex processes and fueled by technological and scientific progress, changes can be detected for subjects and procedures in the building of “technical rules” and in regulatory policies.

In relation to the subjects, it should be emphasized that because of the delicacy of the regulatory function in some cases, it is important to put it in the hands of neutral subjects, free from the arbitrariness of the majority and of politics in general (authorities that look after specific interests). This makes it clear the tendency to attribute to specific authorities the function of *regulation* (a function involving a set of administrative and regulatory powers and relating to justice as well)¹⁶.

In the Italian health legal system there is no regulatory agency.

Nevertheless, over time, both specialized bodies and nontraditional authorities have increased and specialized in the construction of rules for the health sector. This is particularly true when thinking of the expansion of health care across nations (supra-nationality) and the opening of European borders: Technologies make services more easily available to patients. Notwithstanding with the fact that technologies are not limited by territorial regulations and have a transnational dimension¹⁷.

It is true that the organization of health systems, provision of healthcare's planning, the financing arrangements fall within the competence of the Member States, but it is also true that these aspects are increasingly framed in a general regulatory framework, which is affected highly by Community policies (research, free movement of persons and services, sustainability of public finances).

Consequently, in order to achieve, as soon as possible, harmonization in providing health services, based on shared standards, the Member States have equipped themselves with supranational bodies which establish rules on the various aspects of health care e.g. the right to health, patient's cure record and, in particular, drug therapies.

In fact, in 1995, the European system for the approval of medicines was created by the establishment of the European Medicines Agency (EMA). This agency has made significant progress in unifying and improving regulatory practices, as well as rationalizing the necessary paths in make drugs available for use¹⁸.

EMA oversees a number of regulatory procedures and Member states contribute in various ways in building specific systems of health care rules. Experts are appointed and work on an "ad hoc file" and interact with scientific societies and patients, promoting guidelines and/or shared programs that the administrations of the Member States will apply.

The impact of European law on the technical expertise of national health authorities¹⁹, however, goes beyond the paths defined by regulatory agencies and legislators. The Europeanization of certain rights requires a regulatory system set at different levels but having common features because it is important to respect the substance of European citizenship and to give it concreteness. As an example, think of the healthcare linked to the so called "patient mobility".

To this end every initiative, every joint actions and synergies aimed to connect EU rules and national rules, every activity of administrations and monitoring bodies should be supported. This could be one of the targeted effective strategy in the medium term. This would imply the various actors or stakeholders in the system to be involved in the improvement of and satisfaction of health care needs of the European citizen. The latter will move more and more within a context in which scientific progress broadens the boundaries of "national health" and activates those phenomena of administrative resilience capable and not overturn the national characteristics of each of the health

system.

Among the actors, a key role is attributed to the courts. With the increase of their commitment to protecting the right to health and despite many episodes of liberalization and outsourcing in the health sector, have shifted the axis of the involvement of some courts). The involvement of the courts is also influenced by the technologies and scientific progress. There is no reference here to the way of working within the trials but to the fact that technology has contributed to change the categories of “binding” and “discretion” of rules within the activity of health system actors.

As a result, as more and more technology is applied, the right to health and the preservations new aspect and new content becomes stronger.

In that context, as has been rightly pointed out, the need for judicial intervention has been identified in the protection of fundamental human rights and human dignity and indispensable protection of certain principles that characterize significantly the legal frame. Within democratic representative circuit, what is evident in the involvements of courts is continues need for its function, against the inertia of legislators and their inability to develop disciplines capable of respecting the diversity of choice and values across various systems²⁰.

Therefore, if the role of courts is important in the effectiveness of the right to health in technological changing times, then it is questionable as to whether they are prepared to apply the best possible rules (including some highly technical ones) which would aim at providing a legal framework to new technologies and scientific progress.

Whether the courts have experience or no experience, whether they are specialized or not, may unknowingly increase the risk of inequality in settling disputes in the applications of legal framework, rights to health and technological changes. It is equality questionable as to whether traditional judicial procedures would ensure any better outcomes or satisfaction to protect the interest of the various parties²¹. However alternative dispute resolution methodologies may be more efficient²².

In this context it should not be forgotten that the court should take into account the various legal and practical changes around patients' role. In fact, it is noted that a transformation of the patient's legal situation and forms of protection of the right to health, as occurred as a result of the loss of traditional public regulation and the prominent role of public healthcare. These changes influence the role of the courts and the type of the claims and fueling the need for additional forms of protection.

The transformation of the patient's legal situation increasingly requires strong compliance and application of the principle of proportionality. There is also the need for the court to have adequate the professional standards to cope with the new situations.

As has been rightly pointed out, maybe what is important is not the direct knowledge of the non-legal disciplines, but the awareness about the proper relationship that should exist between the general principles of law, on the one hand, and technical rules, on the other. In other words, now, the court must achieve a balance between the constitutional and fundamental values that the right to health implies and demands that technology brings. This activity should consider the delicate assessment of the proportionality of the administrative measures with decisions made on healthcare. It must verify that courts know how the challenge of a modern health system requires an adequate response to the problems posed by scientific progress.

We need to ask ourselves which position should be considered, what is alleged is not the application of technical rules, but the ability to test a scientific hypothesis that goes to demolish the presupposition on which the same rule works.

It must be underlined, then, that confronting significant changes over the last decade about the relationship between law and life sciences in front of the delay of legislator is, the court plays, now, the fundamental role of balance between the growing needs of society and the integration of the results of scientific progress within a legal frame. In fact, “hardly the rigidity of law succeeds in combining nimbly with the changing nature of science and some communication barriers, related to the diversity of language, method and approach, leading to advise caution in the construction of a dialogue with other disciplines”²³.

ISSUES AND DILEMMAS STILL OR ALWAYS OPEN? THE BOUNDARIES OF THE RIGHT TO HEALTH NOWADAYS.

The issues contained within the pages of this contribution affect all the health systems and represent one of its challenges ever. This because in a world in which science and technology play a crucial role, the legal structures and legal culture of a system should be periodically (if not constantly) subject to a review aimed at renewing the reference model in which they move. And this in order to respond appropriately to new needs that, without interruption, occur with the evolution of economic and social reality: the progress of society, in essence, often determines the obsolescence and/or insufficiency of rules²⁴.

Since it is the legal regulation that defines the content of rights, it is clear that is very important for the right to health (positioned in the Olympus of personal rights) an adequate legislation which changes with the times. Nowadays defining the boundaries of the right to health is not an easy task: not only because we are at a time when the debate about the implementation and protection of this primary and fundamental right has to deal with the problems dictated by increasingly stringent budget constraints and by the need to contain public spending; but also - as we have tried to indicate in this contribution - for the difficulty of defining an adequate legal framework for scientific progress that characterizes and influences the sector. Without forgetting that those same boundaries are conditioned by the lifestyles and by the approach to users' health.

It seems therefore, the boundaries metaphor lends itself effectively to representing the challenges which the right to health has to be faced with in this period. In fact, boundaries can be meant figuratively: for example, with regard to the constant and propelling force of the sciences towards new horizons; or in reference to the continuous emergence of new issues deriving from the modification of social relations; as well as from the evolution of users' instances or the irreconcilable restriction of financial resources.

REFERENCES

1. These pages are the result of a multi-year reflection presented in congressional and written reports, i.e. De Angelis M. Alcune questioni giuridiche sulla regolamentazione del progresso tecnologico in sanità. *Diritto & Questioni Pubbliche* 2017; p. 1. The Relationship Between Rules and Technologies in a Modern Healthcare System, ICON_S Congress/International Society of public law "Identity, Security, Democracy: Challenges for public law", Hong Kong 25-27 June 2018.
2. Efficient Latin phrase (which recalls the famous *ubi societas ibi ius*) used by A. Morrone commenting on the sentence n. 162/2014 of the Constitutional Court avoiding the prohibition of the heterologous fertilization (In: <http://www.giurcost.org/studi/morrone0.pdf>).
3. See Chieffi L. La regolamentazione della fecondazione assistita nel difficile dialogo tra le due culture. In *Federalismi.it* [internet] 2015; 21. Negroni A. Trattamenti sanitari obbligatori e tutela della salute individuale e collettiva. In *Forum di Quaderni costituzionali* [internet] 2017. 11.
4. About resilience see Duit A. Resilience thinking: lessons for public administration. In *Public administration* 2015; 94:(2). Boschetti B. La de-strutturazione del procedimento amministrativo. Nuove forme adattative tra settori e sistemi. Pisa: ETS; 2018.
5. Vilella G. *Innovazione tecnologica e democrazia*. Bologna; 2015. p. 64.
6. Cf. Directive PCM 26 February 2009. Moreover, technologies themselves are neutral; are "neither good nor bad, but it is the individual to make them such" see Schulz M. Prefazione. In: Vilella G., editor. *Innovazione tecnologica e democrazia*. Bologna; 2015. p. 8
7. About problems on rules' technique in this field, see the contribution of Malaisi B. La legge sulla procreazione assistita e il drafting. Brevi riflessioni tra diritto e scienza. In De Angelis M., editor. *Tecnologie e salute: alcuni profili giuridici*. Rome; 2016. p. 89-118.
8. Salazar C. Umano, troppo umano...o no? Robot, androidi e cyborg nel "mondo del diritto" (prime notazioni). *Rivista di BioDiritto* 2014; 1: p. 257 and *ivi* see the reference (note n. 8) to the problems presented by Pizzetti G. F. Libertà di autodeterminazione e protezione del malato nel Brain-Computer interfacing: un nuovo ruolo per l'amministratore di sostegno? *Riv. crit. dir. priv.*

2011; 1: 31 ff.

9. “With the term robot we can refer to any machine, not necessarily anthropomorphic, that is equipped with the ability to acquire data and information from the surrounding reality through technological “sensors”, process them using special software and to accordingly act”: Salazar C., *cit.*, p. 259.

10. Salazar C. *cit.*, p. 260.

11. This refers to so called *nudge regulation*. “When we speak about nudge (a term which, translated literally, means” little boost “, or” sting “, or “ gentle push “), we consider the set of tools, based mainly on information, that public authorities could implement to promote certain behavior deemed (by the regulator) desirable “: this says Candido A. La nudge regulation. Interpretazioni dottrinali e prime applicazioni pratiche. 2012. p. 1, in http://www.amministrazioneincammino.luiss.it/app/uploads/2012/07/Candido_Regolazione_nudge.pdf [Internet].

12. The rules of drafting teach, in fact, that not always it is convenient to regulate in this way: cf. De Benedetto M., Martelli M., Rangone N. La qualità delle regole. Bologna; 2011. Morelli A. I controlli sulla qualità degli atti normativi del Governo. In: <http://www.gruppodipisa.it/wp-content/uploads/2011/10/morelli.pdf>. 2011; Foschini F., Brevi cenni di riflessione sul drafting formale e sul drafting sostanziale. Analisi di due facce della stessa medaglia. In: https://www.openstarts.units.it/dspace/bitstream/10077/8846/1/foschini_tigor_IX.pdf. 2013. For an analysis of the role played by soft law in the current globalized world, see Ferrarese M.R. Le istituzioni della globalizzazione. Milan; 2000.

13. About *family learning* and technologies see: Bronzini M., Vicarelli G., From the ‘expert patient’ to ‘expert family’: a feasibility study on family learning for people with long-term conditions in Italy. *Health Sociol Rev.* 2009; 18(2): 182-193; Vicarelli G. Le family learning socio-sanitaire: une approche innovante en éducation thérapeutique. Évaluation de la satisfaction des patients et de leur famille, *Pratiques et Organisation des Soins* 2012 ; 43(3) Juillet-Septembre: 187-195

14. About projects related to wearable technologies see: the Cyberlegs project, a project financed at Community level which allows a better quality of life in subjects with invalidated arts. See http://www.sssup.it/news.jsp?ID_NEWS=4993>emplate=default.jsp; or the projectm-RESIST, another project financed by the EU Commission about the use of wearable technology in order to treat schizophrenia (at <http://www.tech2wearmag.com/2015/04/la-tecnologia-indossabile-contro-la-schizofrenia/>)

15. On network management in healthcare, cf. Visioli O. La disposizione a rete delle organizzazioni sanitarie: introduzione ad un nuovo paradigma sociologico. In: <http://www.>

giornaledicardiologia.it/ allegati/00701_2006_09/fulltext/09-06_09%20638-645.pdf.

16. Regulation function according to OECD (Report on Regulatory Reform, Paris, 1997) refers to “ the diverse set of instruments by which governments set requirements in enterprises and citizens”. For a reconstruction of this function, see La Spina A., Majone G. *Lo Stato regolatore*. Bologna; 2000. p. 23 ff. On the relationship between the function and the quality of rules see De Benedetto M, *L'organizzazione della funzione di regolazione*, in *Studi parlamentari e di politica costituzionale*. 2005, p. 73; Raveraira M. *Qualità della normazione e better regulation nella governance degli interessi*. 2006. In <http://www.federalismi.it/documento/editoriale/Editoriale3.pdf>.

17. See Chieffi L. *Scelte alimentari e diritti della persona: tra autodeterminazione del consumatore e sicurezza sulla qualità del cibo*. In: Del Pizzo F., Giustiniani Bioetica P., editor *Ambiente e alimentazione*. Sesto San Giovanni; 2014. p. 50.

18. <http://www.ema.europa.eu/ema/>. For a list of the regulatory authorities in the field of medicines at international level see <http://www.agenziafarmaco.gov.it/it/content/istituzioni-regolatorie-una-collaborazione-internazionale-fronteggiare-l%E2%80%99ebola>

19. About the role of national administrations in order to integrate the administrative systems and for the harmonization of the rules effects, see, *ex multis*, Cassese S. *Il diritto amministrativo: storia e prospettive*. Milano; 2010. p. 363 ff.; Saltari L., *Amministrazioni nazionali in funzione comunitaria*. Milano; 2007. p. 303 ff.

20. Bin R., Busatta L. *Introduzione*. *Forum: Law and the life sciences*. *Rivista di BioDiritto* 2014; 1: p. 7.

21. On the new role of courts on the interpretation of the rules, see Ruotolo M. *Quando il giudice deve “fare da sé”*. *Questione giustizia* 2018. In. http://questionegiustizia.it/articolo/quando-il-giudice-deve-fare-da-se-_22-10-2018.php. He underlines how today the court can feel “authorized to” go forward “in his already recognized task of trying in every way to obtain solutions conforming to the Constitution” and he does not wish to return to “a closed jurisdiction with respect to the possibilities given by the systematic interpretation (and in conformity with the Constitution)”.

22. See De Angelis M. *The progressive spread of ADR: the example of the health sector*, *Bullettin of the Transilvania University of Brasov* 2011; Series VII - Social Sciences - Law, 4 (53): p. 93-102; Gary A. Balcerzak, Kathryn K. Leonhardt, *Alternative Dispute Resolution in Healthcare*. 2008. In: <https://www.psqh.com/julaug08/resolution.html>

23. Bin R., Busatta L., *cit.*, p. 6.

24. One can rightly speak, in general, about a “right of transition”: see Piva S. Concetti giuridici indeterminati, sindacato del Giudice amministrativo e principi CEDU. Federalismi.it [Internet] 2017; 4.

Artigo apresentado em: Dezembro/2018

Artigo aprovado em: Fevereiro/2019

Conflito de interesses: a autora declara não haver conflito de interesses

Financiamento: não