Between Politics and Expertise

An Italian Perspective on Constitutional Law and Scientific Legitimacy

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The dialectic between the technically (or scientifically) possible and the legally possible, which is implied in decision-making in conditions of uncertainty, raises crucial issues from a constitutional perspective. In particular, the emergence of a new factor of legitimacy – which could be envisaged as a form of "scientific legitimacy" – can be detected and needs to be integrated within the constitutional discourse.

Through an overview of the case law of the Italian Constitutional court, the paper aims at highlighting the possible approaches to the need of a deeper integration of technical and scientific knowledge within the public decision-making processes, in an attempt to strike a balance capable of avoiding the two extremes of scientifically weak decisions on one hand, and of "technical deference" to experts on the other.

I. Introduction

The emergence of "new risks" connected to technical and scientific progress has undoubtedly produced a shift in the balance between private and public sphere. However, even focusing exclusively on the latter, its impact can be clearly detected, having affected each of the three classical branches of state power. Neither the judiciary, nor public administration, nor, most remarkably, the legislative power appear to be immune to the implications brought by technical progress, among which stems the increasingly relevant role played by expert knowledge and scientific findings[1].

From a normative perspective, engaging with the ever-evolving dialectic between the technically (or scientifically) possible and the legally possible requires striking an appropriate balance between the threats and benefits posed from time to time by new technologies, and the social concerns raised by them. Such a balance appears to be the result of a complex alchemy, whereby political and technical evaluations both play a key-role[2]. This state of things raises fundamental issues from a constitutional point of view, in so far as constitutional law aims at taming the exercise of state power and at grounding it in a principle-oriented framework. What could be envisaged as a sort of "scientific legitimacy" is in fact emerging as a new factor of legitimacy for public decision-making at legislative level, and requires careful consideration. How does it interact with the traditionally conceived sources of legitimacy (political and constitu-

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1 In relation to administrative decision-making, see Elizabeth Fisher, *Risk Regulation and Administrative Constitutionalism*, (Oxford-Portland: Hart 2007). On experts' role in judicial proceedings, see Sheila Jasanoff, *Science at the bar. Law, Science and Technology in America*, (Cambridge Mass; London: Harvard University Press, 1995); Eric Barbier de la Serre and Anne-Lise Sibony, "Expert evidence before the EC Courts", 45 *CMLR* (2008), pp. 941 *et sqq.*; Alberto Alemanno, "The Dialogue Between Judges and Experts in the EU and WTO", in Filippo Fontanelli, Giuseppe Martinico, Paolo Carrozza (eds), *Shaping the Rule of Law through Dialogue. International and Supranational Experiences*, (Groningen: Europa Law Publishing, 2009).

2 See, in similar terms, Elizabeth Fisher, *supra* note 1, at p. 246: "decision-making [is] a mix of expertise and democracy, science and values, and politics and knowledge. It has not been the case that there has been a stark choice to be made between 'science' and 'democracy', as all decision-making regimes encompass the two".

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tional)? According to which paradigms can the free discretionary space enjoyed by politics be reconciled with the facts and evidence injected within the decision-making process by technical and scientific knowledge?

Having briefly sketched a theoretical framework for the analysis of the relationship between legal and scientific categories (part II), the article focuses on the problems presented by scientifically controversial issues from the perspective of constitutional adjudication, trying to define how they are translated into constitutional reasoning. Starting from a case study based on the analysis of the Italian Constitutional court's case law dealing with science-related legislation (part III), a paradigm for interaction between political discretion and scientific evidence will be drawn and critically assessed (part IV), focusing in particular on the construction of technical-scientific knowledge as a constraint for political discretion.

II. Law, Science and Technology: Reasons of a Difficult Dialogue

1. From Traditional Dichotomies…

In a cultural atmosphere permeated by "complexity" and by the need of integrating different "visions of the world" (economic, technical-scientific, religious, ...) within the legal system, the interaction between scientific knowledge (and rationality) and law has so far represented a particularly rich area of investigation, due to the foundational claims both branches of knowledge advance. Each being highly self-referential, not only do science and law analyse facts according to their own rules, but they also tend to order them according respectively to what is "just" and to what is "practically possible"[3]. The depth of such differences in approach can easily be grasped when considering basic concepts as those of certainty and necessity on the one hand, and of space and time on the other. This is of course not the place for such a wide ranging inquiry, but it is worth spending a few words at least on the first of the two conceptual couples, before proceeding with the analysis.

The concept of certainty has been significantly reconsidered in both fields, and little remains of the modern "myth" of legal certainty and of the immutability of the natural laws investigated by science. However, those which are now considered as "two uncertainties" do still largely differ. While legal certainty inherently aims at stability, answering to the need of directing human actions according to a predictable criterion[4], scientific certainty finds its premise and its limit in falsifiability[5], thus being subject to continuous re-definition and being rather expressed in terms of probability than of actual certainty. The gap remains unbridged when turning to consider the understanding of necessity in hard sciences and in law: scientific thought is largely based on a naturalistic assumption of necessity, which describes the causal link between two or more elements. Legal reasoning instead structures the connections between its objects in prescriptive terms, thus establishing a relationship between them, which appears to be the result of evaluation and discretion. Hence, the conceptual gap between the necessity underpinning natural laws(*Müssen*), on the one hand, and legal rules(*Sollen*), on the other.

A gap which generates a full array of theoretical and – as it will soon be illustrated – practical difficulties when law and science meet on the same field, be it originally scientific, as with the regulation of new technologies, or legal, as with expert evidence in trials. In all such cases, the dichotomies outlined above collapse, and the dividing line between what is possible in the technical-scientific sphere (i.e. feasible) and what is possible in the legal one (i.e. legitimate) needs to be redesigned.

Different theoretical backgrounds are though not the only obstacle this process encounters, being accompanied by a sort of naivety, which has often characterised the legal approach to science[6]. In fact, un-

3 Astrid Zei, *Tecnica e diritto, tra pubblico e privato*, (Milano: Giuffrè, 2008), at p. 6. On the structural differences running between the legal and the scientific discourse, see Gaetano Carcaterra, "Certezza, scienza, diritto", 39 *Rivista internazionale di filosofia del diritto* (1962), pp. 377 *et sqq*.

4 Norberto Bobbio, "La certezza del diritto è un mito?", 29 *Rivista internazionale di filosofia del diritto* (1951), at p. 151 *et sqq*.

5 Ernest Nagel, *The structure of science: problems in the logic of scientific explanation*, (New York; Burlingame: Harcourt, Brace & World, 1961) and, critically, Paul K. Feyerabend, *Against method: outline of an anarchist theory of knowledge*, (London: Verso, 1978).

6 For an exemplification of some of the features characterising the "ingenuous" attitude of the legal sphere towards science, see Alberto Artosi, "Reasonableness, Common sense, and Science", in Giorgio Bongiovanni, Giovanni Sartor, Chiara Valentini (eds), *Reasonableness and Law*, (Dordrecht: Springer, 2009), pp. 69 *et sqq.*, at pp. 74-78.

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til relatively recently, this approach has tended to go beyond the recognition of methodological strength and evidence-based nature, embracing a neutral and non-evaluative understanding of science, which can be equally fascinating as misleading. Several other branches of knowledge (and especially sociology and philosophy) have been prompt in gaining awareness of the twofold nature of technique, as both a tool and an aim in itself. Legal attitude instead has long seen it as a mere provider of "neutrality and objectivity, which appeared to be lacking in political and legal systems"[7], and placed it outside the reach of criticism, debate and value judgments. Such an understanding has played a significant role in attracting legal regulation of science outside the domain of government, towards that of governance and self-regulation (as in the case of technical standard-setting)[8], on the assumption that better and more reliable results could be achieved by science when enjoying a wide margin of autonomy[9].

According to this traditional construction, the meeting between law and science therefore seems particularly challenging for the former, doomed to step back in font of the dynamism and evidence-based rigour of the latter and, even more, in front of the pervasiveness of technical progress.

Nevertheless, a more careful look has suggested considering the dialogue between technical-scientific knowledge and legal regulation as one of bi-directional influence, where meanings are reciprocally produced and modified by the constant interaction between science and society[10]. Such a change in perspective has highlighted that, if, when facing science, legal categories are undoubtedly under strain, at the same time their role it not merely passive. In fact, "law is not just another site for carrying on a scientific or political debate. Legal disputes over technological risk decision-making are carried on in legal terms. Law has its own internal logic and philosophy"[11], which frames and influences the debates taking place within its domain.

2. …to Contemporary Doubts: Legal Certainty for Scientific Controversies?

This is even more the case when it comes to science policy issues, whereby the decisions to be taken concern matters, which are controversial or unknown within the technical-scientific community itself[12].

Be it for practical or moral reasons, which make it impossible to collect all the relevant information[13], or for disagreements among the experts on how to interpret them, in all such cases science is not (yet) able to give all answers. The balance then inevitably shifts towards political evaluations: in so far as a decision implies the allocation of a risk, as it is the case with risks descending from scientific uncertainty, considerations which are political in nature are necessarily implied[14]. The "harder" concept of govern-

7 Mariachiara Tallacchini, "Legalising Science", in 10 *Health Care Analysis* (2002), pp. 329 *et sqq*, at p. 329. Notable exceptions need to be mentioned as well: among these see in particular Carl Schmitt, "The age of neutralizations and depoliticizations" (1929), in Carl Schmitt, *The concept of the 'political'. Expanded edition*, (Chicago: The University of Chicago Press, 2007), pp. 80 *et sqq*, according to whom "technology is always only an instrument and weapon; precisely because it serves all, it is not neutral. No single decision can be derived from the immanence of technology, least of all for neutrality" (at p. 91).

8 See Harm Schepel, *The constitution of private governance: product standards in the regulation of integrating markets*, (Oxford: Hart, 2005).

9 Hence the problems related to if and to what extent to intervene by means of regulation. On the tension between self-organisation and the government of purpose, in relation to science and technology, see Susana Borrás, "Three tensions in the governance of science and technology", in David Levi-Faur (ed.), *Oxford handbook of governance*, (Oxford: Oxford University Press, 2012), at pp. 431 *et sqq*. The Author highlights how such an arrangement is currently being put under pressure by the "changing societal expectations about the role of science in society. The traditional 'social contract for science' is based on an unveiled positive view of science as an 'ivory tower', in the expectation that science produces reliable knowledge and communicates it to society in a one-way fashion. Dissatisfaction with the 'ivory tower' means that the old 'social contract' is giving way to a new contract, the shape of which is still not clear". Further tensions are determined by the emergence of new kinds of governmental involvement in science and technology policy and by the issues presented by the ownership (and commodification) of technical and scientific knowledge.

10 Such shift is embodied by the co-production paradigm theorised by Sheila Jasanoff, *supra* note 1.

11 Elizabeth Fisher, *supra* note 1, at p. 23.

12 Such issues have alternatively been defined as "trans-scientific": issues which "can be stated in the language of science but are, in principle, or in practice, unanswerable by science" (Giandomenico Majone, "Foundations of Risk Regulation: Science, Decision-Making, Policy Learning and Institutional Reform", in 1 *European Journal of Risk Regulation* (2010), at pp. 5 *et sqq*, at p. 5.

13 For example, when it comes to identifying the exact threshold above which carcinogenic substances have adverse effects on humans. Uncertainty can also be related to the time factor, as in cases of urgency, when a decision needs to be taken before the relevant data is available, or when it is not yet possible to fully determine the consequences related to the use of a technology (e.g. because it is still being developed).

14 Ulrich Beck, *Risk society: towards a new modernity* (1986), (London: Sage, 1992).

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ment therefore re-expands, and with it the role of (hard) law[15]. In this context, several approaches to public (including both administrative and legislative) decision-making under conditions of uncertainty have been developed, ranging from the much debated precautionary principle to standard setting aimed at reducing risks to an "acceptable" or to the "lowest possible" level[16]. The balance between democratic and scientific legitimacy underpinning such approaches, and their regulatory outcomes, has been mostly investigated in relation to executive decision-making[17]. It is in fact within the administrative branch that most risk regulation issues are dealt with: its institutional design, access to scientific expertise and availability of resources all appear more suited to face the highly specific and ever-evolving questions posed by the regulation of uncertainty, and especially by the determination of the acceptable level of risk[18]. However, if from a quantitative point of view risk regulation undoubtedly rests within the administrative branch, it can be argued that, from a qualitative one, primary law-makers play an all but irrelevant role. Rather than taking specific decisions, for which they are poorly equipped, they define the broader policy issues underpinning them. First of all, primary legislation frames the discretionary space within which the administrative branch can legitimately move; secondly, and most importantly (at least in this context), it represents the arena where the balance between the freedom characterising political discretion and the factual constraints represented by scientific evidence first takes the shape of law, being cristallised in general and abstract terms.

III. Scientific Uncertainty and the Constitution: A Case Study from Italy

Constitutional adjudication offers a fruitful perspective to investigate both the content and the structure of the balance struck by primary law-makers. In reviewing the exercise of Parliaments' normative powers in relation to scientifically controversial issues, constitutional courts can provide indicators under three respects: whether it is possible to envisage the emergence of a (legal) paradigm for the interaction between science and politics; how risk-related issues are translated into principle-oriented constitutional reasoning; and, which aspects the political decision-maker needs to consider in such cases, in order to enact constitutionally sound legislation.

The case law of the Italian constitutional court (hereinafter, the Court) provides some interesting elements to approach the questions outlined above. In general, the Court's attitude towards science and technique has mostly tended to be framed according to the dichotomy discussed above. However, it is possible to identify a small but consistent line of case law, developed since the late 90s, representing a meaningful development within such more traditional trend.

Before dealing more specifically with the relevant judgments, some background aspects need to be mentioned. The first relates to the Court's access to scientific evidence. Although the rules of procedure allow the Court to request documents and data from the parties, such possibility has seldom been exploited. The Court's knowledge of the facts is therefore largely based on the (usually little) evidence presented by the parties and on "common sense"[19]. Direct contact with scientific knowledge is more than exceptional, and facts come into play only indirectly, in a reasoning which remains focused on principles and precedents[20].

This provides a partial explanation for the second aspect, concerning the Court's rather traditional approach when examining science-related issues. In fact, it tends to assume a strict separation between

15 As Elizabeth Fisher, *supra* note 1, at pp. 9-10 observes, "the state and its conceptual baggage", although "much maligned, are still the starting points for conceptualising this area of decision-making. In part this has to do with the fact that it is only sovereign states that have the innate power to regulate risk …".

16 For a typology of risk regulation strategies, see Giandomenico Majone, *supra* note 12, at pp. 11 *et sqq*. Literature on the precautionary principle is extremely rich. For a comparative overview, see Joakim Zander, *The Application of the Precautionary Principle in Practice*, (Cambridge: Cambridge University Press, 2010); for an influential critique Cass R. Sunstein, *Laws of Fear. Beyond the Precautionary Principle*, (Cambridge: Cambridge University Press, 2005).

17 See for example Michelle Everson, Ellen Vos (eds), *Uncertain Risks Regulated*, (Oxon-New York: Routledge-Cavendish, 2009) and Maria Weimer, "Risk Regulation and Deliberation in EU Administrative Governance – GMO Regulation and its Reform", 5 *European Law Journal* (2015), at pp. 622 *et sqq*.

18 Elizabeth Fisher, *supra* note 1, at pp. 19 *et sqq*.

19 Paolo Veronesi, "Le cognizioni scientifiche nella giurisprudenza costituzionale", 3 *Quaderni Costituzionali* (2009), at pp. 591 *et sqq*, at p. 604.

20 Roberto Bin, "La Corte e la scienza", in Antonio D'Aloia (ed.), *Bio-tecnologie e valori costituzionali. Il contributo della giurisprudenza costiutioznale*, (Torino: Giappichelli, 2005), at pp. 5 *et sqq*.

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the world of law and that of technique, where the latter is characterised by objectivity and detachment from social, political and economic interests. Although the Court's awareness of the instability of technical-scientific certainties emerges in several judgments[21], it does not seem to be accompanied by a similar attitude towards the neutrality of technique. The alleged immunity of technical issues from value judgments is noticeable in particular in relation to technical legislation: the neutrality of science and technique has in several cases justified derogations (though not macroscopic) from constitutional principles such as the hierarchy of the sources of law[22] and the allocation of competences between State and Regions[23]. However, when it comes to scientifically controversial issues, the picture becomes more complex. Until 1998, the criterion followed by the Court in the review of science-related legislative choices tended to allow the Parliament an almost unlimited discretionary space. In dismissing an application against the alleged unconstitutionality of the statutory distinction between "habitual abuse" and "chronic addiction" to alcohol or drugs, due to the impossibility to ascertain it at a scientific level, the Court stated that a contradiction between science and law could lead to a declaration of unconstitutionality only when legislative discretion went against "undisputed scientific findings"[24]. The "binding effect" of technical-scientific facts was thus limited to uncontroversial issues, whereas in all other cases the law-maker benefitted from a sort of presumption of constitutional conformity.

The last remark concerns the *status* of the precautionary principle within the Italian constitutional framework. Although being formally enshrined in primary legislation[25], mostly as a consequence of EU law, such principle does not belong to the constitutional catalogue. It has been noted how the Constitutional court has on some occasions adopted a "precautionary attitude"[26], or used the precautionary principle as a tool for balancing competing interests (economic, health-related and environmental)[27] but, notwithstanding the parties' claims, it has never adjudicated a case on the grounds of the precautionary principle. The judgments that will now be examined, however, outline the gradual emergence of a different and specific standard of review to be applied when dealing with science- and technology-related uncertainties[28].

1. Clinical Trials

A first couple of judgments (n. 185/1998 and n. 274/2014) deal with access to "alternative" pharmaceutical treatments as part of the right to health. In 1998, the professor and physician Luigi Di Bella announced that his therapy, based on somatostatin treatments, although not supported by official clinical trials, could defeat cancer; as a consequence, several other physicians started to provide the treatment to their patients and several courts were called upon to decide on patients' claims to have free (i.e. provided for by the NHS) access to it[29]. Claims were grounded (and in many cases upheld) on the constitutional right to health (Article 32 of the Constitution), which would have included the right for terminally ill patients to have free access to therapies "which are

21 See decision n. 114/1998 and Fiammetta Salmoni, *Le norme tecniche*, (Milano: Giuffrè, 2001), at pp. 98 *et sqq*. All the Constitutional court's judgments quoted are available (in Italian) on the Internet at www.cortecostituzionale.it .

22 See for example decisions nn. 103/1957 and 36/1954.

23 See decisions nn. 61/1997 and 21/2010.

24 Decision n. 114/1998. A similar statement can be found also in a more recent decision (n. 342/2006) concerning GMOs, where the Court allowed Parliament "a wide margin of discretion in determining the content which appears to be more appropriate to the achievement of the relevant statutory aims, so that a legislative provision can be found to be unconstitutional only when the level of uncertainty of the scientific evidence on which it is based is so significant to determine the arbitrariness or the irrationality of the provisions under review".

25 See for example the "Environmental Code" (legislative decree n. 152 of 3 April 2006). On the precautionary principle in the Italian legal system see Luciano Butti, *The precautionary principle in environmental law*, (Milano: Guiffrè, 2007).

26 Giuseppe Manfredi, "Note sull'attuazione del principio di precauzione in diritto pubblico", 3 *Diritto pubblico* (2004), at pp. 1075 *et sqq*, at p. 1101.

27 Giovanni Di Cosimo, "Corte costituzionale, bilanciamento di interessi e principio di precauzione" (*Forum di Quaderni Costituzionali Rassegna*, 10 March 2015), <http://www.forumcostituzionale.it/wordpress/wp-content/uploads/2015/03/dicosimo.pdf> accessed 27 January 2016.

28 Cases will not be grouped chronologically but rather following a substantial criteria. It has to be kept in mind that those analysed do not represent the entirety of the cases in which the Constitutional Court has dealt with scientifically controversial issues: for a broader overview, see Michele Ainis, "Le questioni scientifiche controverse nella giurisprudenza costituzionale", in Antonio D'Aloia, *supra* note 18, at pp. 23 *et sqq*.

29 For an overview of the Di Bella case see Francesco Paolo Colucci, Lorenzo Montali, "Relevance of the Di Bella case in the relationship between people and official medicine", 3 *Epidemiologia e prevenzione* (2003), at pp. 180 *et sqq*.

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known to have a certain degree of possible effectiveness"[30]. To face "the extraordinary ongoing situation" the Italian government established, by means of a decree, that a clinical trial should be carried out by the Ministry of Health in order to determine the effectiveness of the therapy[31]. Soon after, the trial ascertained its scientific inconsistency. However, while the issue was still being disputed, the Court was called upon to decide whether several provisions of the decree were compatible with the constitution[32].

The Court found that the decree had wrongfully omitted to provide for economic support to those terminally ill patients, who, although not included in the ongoing clinical trial, could have access to the therapy at their own expenses (thus violating the equality principle as stated in Article 3 Const.)[33]. In doing so, the Court treated terminally ill patients' expectations (or rather hopes) connected to the clinical trial as falling within the "minimum content" of the right to health[34], due to their extreme condition, even if such right does not include "an obligation for the State to provide for free whatever therapy citizens ask for"[35]. The question then arose of who was in charge of delimiting the field of admitted therapies. In an *obiter dictum* (para 8), the Court affirmed that the competence to establish, according to the law, what falls within the concept of "therapy", and therefore within the reach of the right to health, rests solely with the relevant technical-scientific organs, whose evaluations are essential and not reviewable by the Court itself[36].

Beyond the merits of the Di Bella therapy, which has been found to be scientifically unsustainable, critics have noted how the Court has in practice deferred "the responsibility of determining to what extent a right is a right [...] to science"[37], as represented by governmental expertise, delimiting an area of "reserved technical competence".

A partially similar factual background happened to be presented to the Court in 2013-2014, when another clinical trial was ordered by law[38] to test the effectiveness of the "Stamina treatment". This controversial "therapy" for degenerative brain diseases[39] had arisen an extremely heated public debate, accompanied by judicial claims to have access to the treatment and by the strong opposition of the scientific community worldwide[40], and had soon after turned out to be an even worse case of "junk science" leading to criminal responsibility of its proponents.

The scientific weakness of the Stamina treatment was already claimed by several authoritative voices at the time of the decree (and of the subsequent law), so that is can be questioned whether the legislative decision was actually taken in conditions of uncertainty. However, no doubt was left when the Court was called upon to review the law establishing the clinical trial, the radical inconsistency of the Stamina treatment having been already assessed by the appointed ministerial committee. No trace of the partial uncertainty under which the Government and the Parliament had originally acted, was present when the Court rendered its judgment, which is one

30 In these terms the claim filed by the Council of State to the Constitutional Court (it would violate art. 32 Const. to deny "la somministrazione gratuita di farmaci di cui siano nota una certa efficacia terapeutica a malati terminali, cui va riconosciuto il diritto a seguire una via terapeutica che ha un margine di possibile efficacia").

31 See decree n. 23 of 17 February 1998, and law n. 94 of 8 April 1998; all the legislation quoted is available (in Italian) on the Internet at www.normattiva.it .

32 See decision n. 185/1995.

33 The law was then amended in order to comply with the Constitutional court's decision (decree n. 186 of 16 June 1998 and law n. 257 of 30 July 1998); having been in turn brought to the Court, the claims were dismissed (decision n. 188/2000).

34 And should therefore be granted in conditions of equality (decision n. 185/1998, at para. 9).

35 Mariachiara Tallacchini, *supra* note 7, at p. 331.

36 See decision n. 185/1998, at para. 8: "Questa Corte non è chiamata a pronunciarsi, in alcun modo, circa gli effetti e l'efficacia terapeutica di detto trattamento […]. Non è chiamata, né potrebbe esserlo, a sostituire il proprio giudizio alle valutazioni che, secondo legge, devono essere assunte nelle competenti sedi, consapevole com'è del rilievo che, in questa materia, hanno gli organi tecnico-scientifici".

37 Mariachiara Tallacchini, *supra* note 7, at p. 332.

38 Law n. 57 of 23 May 2013, converting the decree n. 24 of 25 March 2013, which had temporarily allowed for the continuation of all those treatments which had already begun – for an overview of the "Stamina case" see Antonio Scalera, "Brevi note a margine del 'caso Stamina'", 10 *Famiglia e diritto* (2013), at pp. 939 *et sqq*; see also Giacomo D'Amico, "Il volto compassionevole del diritto e la *dura scientia*", 2 *Quaderni Costituzionali* (2013), at pp. 420 *et sqq*. The clinical trial was not completed due to the impossibility of even considering the treatment as a therapy. The claim was dismissed by decision n. 274/2014.

39 The treatment was being supplied by the Hospital of Brescia, when an injunction adopted by the Italian Medical Agency (AIFA) prohibited its continuation due to the lack of evidence concerning the treatment's effectiveness.

40 Beyond the national boarders, see the debate on *Nature*, available on the Internet at http://www.nature.com/news/italian-stem-cell-trial-based-on-flawed-data-1.13329 accessed 27 January 2016.

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of the main differences to the Di Bella case. Notwithstanding its scientific weakness, the Court did not quash the legislative act on the grounds of the exceptional circumstances, which had led to its adoption[41]. Nevertheless, reaffirming the essential role of scientific expertise, which had reported negatively on the treatment's effectiveness, in this case the Court considered patients' expectations below even the minimum content of the right to health, thus finding the restricted access criteria (based on temporal priority) established by the legislative provision (Article 2 (2), decree 24/2013)[42] not to be unreasonable.

2. Controversial Therapies

The assumptions on which the two judgments considered so far are based, have come into play also in two decisions adopted in 2002 and 2003[43] concerning two regional laws that, by means of similar provisions, had established a temporary ban on certain therapies (among which electroshock and lobotomy) within the respective territories. One of the two provisions, in particular, had been adopted in response to a regional campaign, supported by more than 3.000 people, asking the prohibition of such therapies on the grounds of their uncertain effectiveness and of their potentially adverse effect on patients' physical and mental health. When presented to the regional assembly, the draft legislative proposal was supported by references to several legal documents (ranging from UN resolutions to regional guidelines) concerning the use of neurosurgical therapies[44], but not by scientific evidence.

Both provisions were quashed on the grounds of the central state's competence in establishing fundamental principles in the field of healthcare, to which regional laws must comply. In doing so, nevertheless, the Court established some general principles for legislative intervention in the field.

Starting from the assumption that legislative power should defer the choices related to medical therapies' admissibility to the physicians' autonomy, on the grounds of the scientific and experimental data available[45], the Court went on to establish a general criterion. Although the field of medicine and therapies is of course not precluded from legislative intervention (as in cases concerning risky therapies), such intervention "cannot derive exclusively from political discretion", but needs to be grounded "on the state of scientific knowledge and evidence, as provided by national and supranational organs and institutions, given the essential role played by technical-scientific institutions in such field"[46]. The regional provisions were therefore found to be unconstitutional in so far as they were the outcome of an autonomous legislative choice, lacking a sound technical-scientific background, verified by the competent institutions, and concerning therapies, which, though not unanimously accepted by the specialists, are neither new nor experimental[47].

3. Medically Assisted Reproduction

This sort of "scientific boundary" to political discretion has found further validation in the judicial saga concerning the legislative framework established by

41 On the reasons that may have brought the Court not to strike down the law see Giacomo D'Amico, "Caso 'Stamina': la 'lotta per la salute'" (*Forum di Quaderni Costituzionali Rassegna*, 1 February 2015), http://www.forumcostituzionale.it/wordpress/wp-content/uploads/2015/01/nota_274_2014_damico.pdf accessed 27 January 2016; see also Giuliano Sereno, "Il 'caso Stamina' all'esame della Corte costituzionale: un esito condivisibile sorretto da una motivazione lacunosa", (*Osservatorio Costituzionale*, January 2015) http://www.osservatorioaic.it/il-caso-stamina-all-esame-della-corte-costituzionale-un-esito-condivisibile-sorretto-da-una-motivazione-lacunosa.html accessed 27 January 2016.

42 The same provision was found by the European Court of Human Rights (hereinafter ECtHR) not to be in contrast with the right to health as protected by art. 8 and 14 ECHR in the case *Durisotto v. Italy* (application n. 62804/13), ECHR 152(2014) 28.05.2014: recalling *Hristozov and others v. Bulgaria* (nn. 47039/11 and 358/12, ECHR 2012) the ECtHR considered that on the one hand States enjoy a wide margin of appreciation when establishing restrictive criteria for the access to compassionate therapies (see also *Evans v. United Kingdom* [GC], n. 6339/05, ECHR 2007 I and *S.H. and others v. Austria* [GC], n. 57813/00, ECHR 2011); on the other hand that it is not for the international jurisdiction to reconsider the competent national authorities' evaluations (i.e. technical-scientific institutions) concerning the acceptable level of risk for patients in order to have access to therapies undergoing clinical trials.

43 See decision n. 282/2002, concerning regional law (Marche) n. 26 of 13 November 2001 (on which see Elisa Cavasino, "I 'vincoli' alla potestà legislativa regionale in materia di "tutela della salute" tra libertà della scienza e disciplina costituzionale dei trattamenti sanitari", *Giurisprudenza Costituzionale* (2002), at pp. 3282 *et sqq.*) and decision n. 338/2003, on regional law (Piemonte) n. 14 of 3 June 2002.

44 See the regional legislative proposal n. 5, 24 July, 2000, available on the Internet at http://www.consigliomarche.it/banche_dati_e_documentazione/iter_degli_atti/pdl/pdf/pdl5.pdf accessed 27 January 2016.

45 Para. 4, decision n. 282/2002.

46 Para. 5, decision n. 282/2002.

47 Para. 8, decision n. 282/2002.

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law 40/2004 on medically assisted reproduction. The fact of being a clearly "value-oriented" law[48], aimed at providing a strong protection to the embryo, notwithstanding potentially adverse effects on the woman, made it highly controversial from the outset, both within and outside Parliament[49]. Among the most criticized provisions were those concerning the number of embryos which could be implanted (limited to three) and their contemporary implant; the impossibility to carry out a pre-implantation diagnosis to detect the presence of genetic illnesses; and the ban on third-party gamete donation in case of irreversible sterility of one of the members of the couple. Since its approval in 2004, law n. 40 has been subject to a referendum (which failed to reach the minimum threshold of voters), to three adverse judgments of the constitutional court (nn. 151/2009, 162/2014 and 96/2015) and to an overall process of judicial re-writing (especially with regard to pre-implantation diagnosis)[50].

The 2009 decision of the Court quashed the limit of three embryos as well as the requirement of their contemporary implant, leaving it to the physician to determine both aspects case by case. The provision was in fact found to be unreasonable under articles 3 and 32 Const., because it imposed the same treatment to all women regardless their individual conditions, thus representing a potential threat to their health – and to the embryos'. The 2014 decision went further striking down the ban on third-party gamete donations in cases of irreversible sterility[51]: the Court found it unreasonable to prevent the access to this reproductive technology to couples for which it would have represented the only available option, thus frustrating their "right to parenthood" (derived from Articles 2, 3 and 31 Const.), and infringing the psychological dimension of the right to health (Article 32).

In both decisions the Court stressed (recalling decisions n. 282/2002 and n. 338/2003) the importance of the physician's autonomy and responsibility, which should represent the general rule when dealing with therapeutic decisions. Furthermore, the Court explicitly stated that "the constitutional case-law has affirmed in several occasions that scientific acquisitions represent a limit for legislative discretion" (decision n. 151/2009), which is not unlimited when dealing with therapeutic issues, having to respect the scientific findings as provided by technical institutions and organs (n. 162/2014).

IV. Science and Political Discretion, through the Lens of Reasonableness

A combined reading of the judgments discussed above brings to light the presence of some recurring elements in the constitutional review of scientifically controversial issues concerning the medical-therapeutic field.

First of all, the Court recognises a wide space for the autonomy of technical-scientific actors. The category embraces physicians, in their choice of the therapy which suits best the individual case, and experts, represented by technical-scientific institutions at national and supranational level. In both cases, their decisions enjoy a sort of "reserved technical competence", being put outside the constitutional review's reach. Furthermore, the contribution of such institutions is considered to be "essential" in providing qualified scientific knowledge to the bodies in charge of legislative decision-making. Thirdly, and consequently, political space for manoeuvre is not unlimited when it comes to scientific issues and evidence[52]. The combination of such elements could therefore provide a starting point in order to define the contours of a constitutional paradigm for the interaction between science and political discretion. In these respects, the emergence of the concept of "scientific reasonableness"[53] has been suggested. Such concept,

48 Simone Penasa, "Converging by procedures: Assisted reproductive technology regulation within the European Union", 3-4 *Medical Law International* (2012), at pp. 371 *et sqq*.

49 For an overview of the content of law 40/2004 and of the legal, ethical and medical problems is presented from the outset, see Vittorio Fineschi, Margherita Neri, Emanuela Turillazzi, "The new Italian law on assisted reproduction technology (Law 40/2004)", 31 *Journal of Medical Ethics* (2005), at pp. 536 *et sqq*, and Andrea Boggio, "Italy enacts new law on medically assisted reproduction", 5 *Human Reproduction* (2005), at pp. 1153 *et sqq*.

50 At international level, the blanket-ban on pre-implantation diagnosis was found by the ECtHR to be in contrast with art. 8 ECHR in *Costa and Pavan v. Italy* (application n. 54270/10). See in particular paras. 68-69, where the ECtHR states that, although the provision has moral and ethical implications, on which States normally enjoy a wide margin of appreciation, what is to be decided is whether it is proportionate, in relation to the legal system as a whole (and thus also in relation to the possibility of therapeutic abortion).

51 On the ban on third-party gamete donations see also the ECtHR decision in *S.H. and others v. Austria* (application n. 57813/00).

52 Andrea Morrone, *Il bilanciamento nello stato costituzionale. Teoria e prassi delle tecniche di giudizio nei conflitti tra diritti e interessi costituzionali*, (Torino: Giappichelli, 2014), at pp. 62 *et sqq*.

53 Simone Penasa, "La 'ragionevolezza scientifica' delle leggi nella giurisprudenza costituzionale", 4 *Quaderni Costituzionali*, (2009), at pp. 817 *et sqq*.

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representing a further dimension of the reasonableness principle[54], would imply that "the legislature [...] is not the main regulatory tool emerging within the medical context. Science itself, in the form of self-regulation and expertise, acts as a direct regulatory tool", parliamentary intervention being thus "limited and oriented" by a set of criteria[55].

Although it has so far been drawn mostly from medical-related issues, such concept seems in principle capable of being brought beyond that specific field, representing a first step towards the development of a general standard of review when dealing with scientifically controversial issues[56]. While waiting for further developments in the case law, it is possible to assess such paradigm in two respects.

The first concerns how scientifically controversial issues are framed within the constitutional discourse. Assuming reasonableness as the key-concept, it is necessary to clarify to which of its three classical branches, as developed by the Italian constitutional Court (equality; rationality/non arbitrariness; reasonable balancing of constitutional interests) the paradigm belongs, if any. A legislative provision which is not based on experimental evidence, or which plainly disregards it, thus being scientifically weak, could be compared to a provision that is based on a (substantial) misrepresentation of facts[57]. Therefore, the "minimum threshold" of scientific adequacy the Court requires legislation to meet, seems to belong to the rationality/non arbitrariness branch of the reasonableness standard. Read in this sense, scientific reasonableness would serve the aim of securing sound scientific basis to political-decision making.

The concern of preventing scientifically weak legislation has played a central role in the judgments considered: in more than one case the issues at stake, besides being scientifically controversial, were also charged with a heavy ethical and political meaning. This has often resulted in a marginalisation of expertise's contribution to the decision-making process, in favour of a strongly (as in the electroshock judgment), if not exclusively (as in the medically assisted reproduction judgments), value-oriented approach. This institutional and cultural background has surely affected the Court's approach to scientifically controversial issues, and should be kept in mind when moving on to consider a further aspect emerging from the cases examined so far.

The Court assumes that when it comes to science-related issues, the Parliament does not enjoy an unlimited discretionary space, with technical-scientific knowledge representing a constraint. It is then necessary to define which kind of boundary is imposed on legislative discretion by technical-scientific knowledge (and in particular, whether it is of a substantial or procedural nature). As it has been suggested above, the presence of "undisputed scientific evidence" can actually represent a substantial boundary for political discretion, beyond which decision-making would not be the rational outcome of a deliberative process, but rather an arbitrary (and "unilateral") determination[58], given the high degree of reliability (if not actual certainty) that technical-scientific expertise can provide in such cases.

Nevertheless, a difficulty with this assumption can be easily pointed out when it comes to scientifically controversial issues, where scientific evidence is disputed, incomplete, or unavailable. In such cases, adopting a substantial approach to scientific reasonableness, where the evidence provided by technical-scientific expertise would act as a limit to legislative discretion, does not seem the best option, as it might result in an abdication of responsibility on the part

54 In the Italian constitutional context, the reasonableness principle is rooted in the principle of equality, stated in Art. 3.1 of the Constitution ("All citizens have equal social dignity and are equal before the law, without distinction of sex, race, language, religion, political opinion, personal and social conditions"). However, constitutional interpretation has read this provision so broadly to develop it according to a three-fold dimension: beyond equality and non-discrimination, reasonableness can refer to the rationality/non arbitrariness of the legislative choice or to the reasonable balancing of constitutional interests. Although the merits of the legislative choice remain excluded from the reasonableness review, the Court has not refrained from making an extensive use of the interpretative tools provided by Art 3.1 Const. For an overview of the different dimensions of the reasonableness principle, see Andrea Morrone, "Constitutional Adjudication and the Principle of Reasonableness", in Giorgio Bongiovanni, Giovanni Sartor, Chiara Valentini (eds), *Reasonableness and Law*, (Dordrecht: Springer, 2009), at pp. 215 *et sqq*. It should therefore be kept in mind that the concept of reasonableness developed by the Italian constitutional court does not fully coincide with the reasonableness test, in its British (Wednesbury test) or Strasbourg (proportionality test) versions.

55 Simone Penasa, *supra* note 48, at p. 324. For a wider theorization of the concept of scientific reasonableness as a standard for constitutional review of medical-related legislative provisions see Simone Penasa, *supra* note 53.

56 Such a conclusion is suggested also by the circumstance that each of the three assumptions on which it relies can be found, separately or combined, and perhaps less explicitly formulated, in relation to issues belonging to different branches of the legal system, in particular with regard to the autonomy and importance of technical-scientific institutions. See, for example, decision n. 116/2006.

57 See, in similar terms, also decision n. 342/2006, quoted *supra* note 23.

58 See above, decision n. 114/1998.

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of political actors, disguised as a form of "technical deference". Such an abdication would in turn exacerbate the already well-known problems related to the need to democratise expertise, calling for more active public participation and strengthened transparency and accountability[59].

The assumption of separation according to which the Court tends to approach science and technology could then be particularly misleading in cases where risk allocation is at stake. Treating both science and law "as black boxes, as a separate and secret form of knowledge that only experts may legitimately use"[60] might decrease the overall democratic legitimacy of a decision, without a relevant gain in terms of scientific reliability.

For these reasons, when it comes to scientifically controversial issues, a "lighter" understanding of scientific adequacy seems preferable, where the limit imposed on political discretion is of a procedural kind. A proper and transparent involvement of all the relevant technical-scientific expertise in the decision-making process (for example through mandatory, and not merely occasional inclusion of the relevant expertise in the legislative process) could represent a step in this direction. Without imposing substantial constraints on the breadth of political discretion, this approach seems more suitable to foster the legislative choice's legitimacy and at the same time its scientific soundness. In such a way, rather than considering technical-scientific knowledge as an alternative source of legitimacy, expertise could be effectively integrated within political decision-making and thus perform both of its two functions: an informational one, guaranteeing "a higher level of scientific adequacy" of the decision, and a legitimising one, integrating the "traditional democratic and constitutional sources with the scientific one"[61], without however altering Parliament's discretionary space, and thus the primacy of the principle of democracy.

V. Conclusive Remarks

The previous paragraphs have showed the emergence of an embryonic paradigm for the interaction between scientific evidence and political discretion within the Italian constitutional court's case law. According to this paradigm, scientifically controversial issues enter the constitutional discourse through the logics of reasonableness, and can be framed according to the standard of rationality/non arbitrariness of legislative decision-making, where the acquisition and consideration of scientific evidence would represent a procedural rather than a substantial constraint for political actors.

Beyond the merits of the cases, a final remark can be made, concerning the role of courts in reviewing science-based measures. Institutional settings and design inevitably exercise a deep influence on how constitutional courts operate and refine their argumentative and adjudicatory tools in order to deal with new challenges, such as those represented by science-related uncertainties. The cases examined and the paradigm of "scientific reasonableness" discussed above do not represent an exception, and their generalizability should therefore not be overestimated. Nevertheless, while different approaches aiming at including the quality and adequacy of science related-measures within the reach of judicial review are being developed across Europe[62], the Italian case can serve as a reminder of the role that law in general, and constitutional principles in particular, can play. What this article suggests is that, in order to continue performing their role as "guardians of the Constitution" when facing technical complexity, constitutional courts do not necessarily need to transform themselves in experts, and to struggle with scientific technicalities; not only are they poorly equipped to perform such task, but it also does not fall within their institutional purpose. While a closer engagement with facts and evidence could benefit the overall (political and scientific) legitimacy of science-based legislation, constitutional courts have at their disposal the potential embedded in constitutional principles, which, if developed, can represent a powerful tool to cope effectively with the challenges presented by the techno-scientific progress.

59 Sheila Jasanoff, *The fifth branch. Science advisers as policymakers*, (Cambridge Mass; London: Harvard University Press, 1994).

60 Mariachiara Tallacchini, *supra* note 7, at p. 330.

61 Simone Penasa, *supra* note 48, at p. 308. The Author also envisages a third function: "a legitimacy one, as [expertise involvement] guarantees at least a presumption of legitimacy in favour of political decisions when checked in the light of a constitutional framework".

62 Ellen Vos, "The European Court of Justice in the face of scientific uncertainty and complexity", in Mark Dawson, Bruno De Witte, Elise Muir (eds), *Judicial Activism at the European Court of Justice*, (Cheltenham-Northhampton: Edward Elgar, 2013), at pp. 144 *et sqq*. The Author points out the changes in the European Courts' attitude towards technical complexity, from a deferential approach to playing more active role.

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