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on
Reasonableness as a criterion for constitutional justice at national, supranational and international level
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Towards new dimensions of the reasonableness principle as a criterion of constitutional adjudication? The paradigmatic case of controversial scientific issues.

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(draft version)

The aim of this paper is to identify and critically analyse a scientific dimension of the reasonableness principle, intended as the attitude of the Italian constitutional Court to involve into the constitutional adjudication elements and data derived from the scientific context. Through the analysis of the constitutional case-law, the effects of this inclusion will be evaluated, from a endogenous perspective with regard to the reasoning of the Court and from an exogenous (institutional) viewpoint, with regard to the effects on the relation between constitutional Court and other constitutional powers, especially the discretionary exercise of legislative power within the medical dimension.

1. Drawing the boundaries (threshold): reasonableness as a legal (jurisprudential) concept in ongoing expansion.

The genesis of the legal concept of reasonableness strictly conditions its substantial development and the range of its concrete application. Reasonableness is therefore a legal concept with a "case-law" origin. More precisely, it could be considered as an expression of the creative activity of constitutional adjudication, which has gradually considered it – together with the principle of legal and constitutional order coherence – as an "essential value" which goes beyond the constitutional text, because it has to be fixed in the core of a civil state's legal order (judgement no. 204/1982).
Reasonableness is an "unwritten" principle, which is "inscribed" in the required genetic heritage of a legal order which wants to be considered substantially constitutional. This is a systematic principle which transcends the written laws[1] and assumes a pervasive efficacy which enlarge its normative boundaries more broad than the traditional ternary territory of article 3 of Italian Constitution (equality principle), characterizes legislative activity in enforcing constitutional rules and principles.
Taking this potential effort into account, the reasonableness principle may be defined as an

1 BIN, *Atti normativi e norme programmatiche*, p. 305.

institutional instrument for the exercise of the legislative function[2], by which the strict link between reasonableness and legislation is shown, and thus, between the constitutional Court and Parliament. Reasonableness may, paradoxically, have a virtuous function in the light of harmonization between Parliament legislative activity and the constitutional scrutiny of the Court, because of it assumes a normative and methodological relevance in both the decision making processes. On the one hand, it is a principle which pertains to legal interpretation means[3] as a compulsory interpretative rule (criteria); on the other hand, even contextually, this principle becomes a necessary condition for the legislative activity, taking part in those procedural conditions belonging to the democratic genesis of laws which guarantee the legitimacy of the written law[4].

Reasonableness therefore may be defined in many ways: firstly, as an argumentative means used by the Court for evaluating constitutional legitimacy of ordinary laws, acting as a parameter by which legislative choices can be measured with regard to the hierarchies[5] of constitutional principles; secondly, it should be considered as a principle which belongs to the whole legal order, definable as "a norm not imposed by any sources, but *presumed* by the pluralism of sources and the open society of the interpreters of the law", expressing in this manner its double nature of interpretative source and concept of constitutional substantial law[6].

Having recognized its origin in the case law of the constitutional Court, it seems to be appropriate to look directly at this source, to find useful criteria for defining its conceptual and applicative ambit, even though recognizing an intrinsic tendency (inclination) towards an on-going expansion. In this regard, the formula expressed by judgement no. 1130 of 1988 of the constitutional Court may be considered a paradigmatic definition, a summary of its nature and to draw the boundaries of a model of scrutiny multiform and potentially contradictory[7].

In that decision, the Court outlines the teleological nature of reasonableness scrutiny as much as its substantial characteristics, stating clearly that, as long as there is no need for an absolute and abstractly defined criteria, reasonableness scrutiny is carried out through evaluations of the proportionality of the means selected by the legislator in its unremitting discretionary power, having regard to the objective demands (needs) to comply with (satisfy) or to the aims which it wants to obtain, considering the circumstances and limits concretely existent". Through this jurisprudential crystallisation of an already "open" legal concept, the Court preliminarily specifies the contents which

2 Lorello, *Funzione legislativa e principio di ragionevolezza*, in AA.VV., *Alla ricerca del diritto ragionevole. Esperienze giuridiche a confronto*, p. 102, nota 11.

3 Bin, cit., p. 306.

4 Habermas, *Fatti e norme*, quoted by Scaccia, *Gli strumenti della ragionevolezza nel giudizio costituzionale*, Milano, 2000, p. 391.

5 According to Stonesweet, paper, p. 33, «there isn't an absolute standard which can be laid down for determining reasonableness or necessity». Also, Baldassarre, p. 41.

6 Luther, *Ragionevolezza (delle leggi)*, in *Dig. It. Disc. Pubbl.*, XII, Torino 1997, 353ss.; Paladin makes reference to a "verb formula lacking in concrete concept".

7 Silvestri, *Scienza e coscienza: due premesse per l'indipendenza del giudice*, in *Diritto Pubblico*, 2, 2004, pag. 433.

do not belong to reasonableness intended as a constitutional scrutiny technique: the reasonableness of a law cannot be checked on the strength of absolute and abstract criteria, identified ex ante according to a hard-set hierarchy, pointing out therefore the essential role of the "facts"[8] into the scrutiny of reasonableness. Reasonableness as a parameter should acquire an enforcing efficacy (a normative dimension) only through the mediation of facts, which the Court resorts to in order to define relations of axiological prevalence abstractly unpredictable[9].

But from the definition derived by the constitutional case-law it is possible to draw even some *in positivo* contents. Therefore, a strong instrumental and teleological bond emerges, which connects reasonableness with proportionality, expressing the double nature of constitutional adjudication: the scrutiny of the adequateness of the norms with regard to the facts to be regulated is added to the traditional function of "rationality scrutiny" with regard to constitutional principles. In this way, a further character of reasonableness is revealed: its *neutrality* before the law, alternatively configuring both as an intrinsic quality and as a sanctioning technique of the law during whatever legislative process a balanced relation between norms and facts is not guaranteed.

Within the scrutiny of reasonableness, therefore, there may be a checking of the proportionality of legislative means compared with normative aims (required by the legal order) and concrete demands to satisfy. At the same time, as a condition to be complied with by the legislator, it will be necessary to verify that circumstances and limits concretely subsistent have been taken into consideration in the decision-making process as objective parameters of evaluation of legislative choices. Therefore, the reasonableness of a law can be predicated taking into account two objective elements: legislative ratio and social contexts[10]. However, the evaluation of the law according to its ratio and to the contexts to which it has to be applied finds a "dike" (quoting an expression of constitutional Court, judgement no. 32/2005) in the discretionary nature of legislative power, which guarantees a margin of decision-making autonomy: a margin which is variable and flexible, depending on the concurrent influence of the normative efficacy of the facts and on the incisiveness of constitutional scrutiny.

Starting from the first variable – which is assuming an ever increasingly important role within scientific and medical context – facts has assumed an autonomous legal relevance based on "the normative efficacy which in an institutional manner the facts are able to express"[11]: the legislator must take into consideration the normative efficacy of facts, because the legislative regulation assumes as a precondition concepts of reality which are independent from the same legislative activity, without which legislative regulation becomes totally incomprehensible and it is even impossible to define it as

8 Bin, cit., p. 334.

9 Scaccia, cit., p. 19.

10 Morrone, *Il custode della ragionevolezza*, pag. 461.

11 Ivi, pagg. 465-466.

a system of norms[12]. In this respect, it seems reasonable to recognize that among the circumstances and limitations concretely existent – among the facts which both the legislator and constitutional Court in exercising their correspondent functions have to take into account – also also those having a technological and scientific nature must be considered[13].

Considering the latter variable – the intrusive degree of constitutional scrutiny into the merit of legislative choices – the attitude of the constitutional Court may appear slightly (prima facie) contradictory. A consolidated orientation of constitutional case-law has constantly recognized that the Court may not substitute the legislator's discretionary choice with its own evaluation, in this way (even apparently) excluding the merit of legislative options from the target of constitutional scrutiny[14]. Otherwise, this limitation, as it has been stressed above, becomes inevitably porous, because even if we recognize that the discretionary power of the legislator represents a dike against constitutional adjudication, this dike can be overcame, although only when the legislative choices describe a legislative product as absolutely and manifestly unconstitutional (according to judgement no. 32/2005).

It is to the Court's responsibility to clarify what this redundant constitutional illegitimacy consists of, through a case by case approach, because the formula derivable from constitutional case-law seems to be definable more as an openness clause to further contents than as a closing clause aimed to guarantee an accomplished (irrefutable) ambit of discretion for the legislator[15].

Once again, therefore, the substantially normative content of the facts is stressed, dealing with a genetically open nature - “disposable” according to the reasoning of the Court – of the reasonableness principle, accordingly definable as an essential and inescapable moment because it allows for the communication between abstract (written) provisions and the concreteness of human contexts[16]. Therefore, what kind of contents should the reasonableness principle be composed of? Which criteria should the legislator strictly refer to in its own regulatory function, which constitutional Court accomplishment should be called to guarantee, undoubtedly limiting in this way legislative discretion[17]?

The initial methodological assumption of this paper applies the open nature of the reasonableness

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12 Ibidem.

13 Camerlengo, *I poteri istruttori della Corte costituzionale e l'accesso degli elementi scientifici nel giudizio di costituzionalità*, in D'Aloia (ed.), *Bio-tecnologie e valori costituzionali. Il contributo della giustizia costituzionale. Atti del seminario di Parma svoltosi il 19 marzo 2004*, p. 175.

14 Ex plurimis, sentenza 190/2001, according to which "esula dai poteri di questa Corte contrastare con una propria diversa valutazione la scelta discrezionale del legislatore circa il mezzo più adatto per conseguire un fine, dovendosi arrestare questo tipo di scrutinio alla verifica che questo tipo di scrutinio alla verifica che il mezzo prescelto non sia palesemente sproporzionato".

15 Particularly, Bin, *Atti normativi*, cit., p. 265, according to whom "la discrezionalità del legislatore risulta definita in base ai canoni che la Corte costituzionale impiega nel giudizio sulle leggi (...) impliciti nel sistema costituzionale”.

16 Lavagna, *Ragionevolezza e legittimità costituzionale*, in Aa. Vv., *Studi in memoria di Carlo Esposito*, Cedam, 1972, p. 1577.

17 Bin, cit., p. 266.

concept to the medical and scientific fields, to individuate which conduct criteria should inspire the legislator in harmonizing facts and provisions, taking into consideration the methodological "guidelines" provided by the constitutional Court's recent case-law. Accordingly, the paper's theoretical starting point recognizes that the peremptory issue within the scrutiny of reasonableness of legislative choices is related to the *quomodo* of this kind of constitutional scrutiny. The definition contained in the judgement no. 1130 /1988 can be decisive in understanding the Court's reasoning, because it overstates constitutional scrutiny area up to including the scrutiny even of the "*methods and criteria*" used by the legislator to achieve legislative product[18].

In other words, the matter in question is to what extent are constitutional judges allowed to retrace the legislator's evaluative process and the resulting value-assessment, to reach their own, autonomous, balance[19]. According to this perspective, two concerns become more decisive: the role of the facts as an essential means in the rationality scrutiny of the laws and the measures by which the legislator can legitimately "query" the facts to derive elements useful to evaluate legislative choices' reasonableness. The hypothesis proposed tends to demonstrate how this measure should be directly proportional to the degree of the involvement of the law in reality to regulate, particularly in the medical and therapeutic field.

2. "Science-related" legislative issues: discretionary power of the legislator and new dimensions (applications) of the reasonableness principle.

The genesis (case-law) and the nature (conceptually plural) of the reasonableness principle could contemplate – mainly utilized by the Court – its application (enforcement) to heterogeneous plurality of legislative contexts[20], with a growing margin of appreciation of the proportionality, consistency and adequacy of legislative choices, even having regard to their own merit. The more the (statutory) law "enters" into the facts – scientific controversial issues in our extent – regulating even the merit of scientific techniques (f.i. Law 40/2004 in human assisted reproduction) applicable to health and human life[21], the scrutiny of constitutional Court becomes proportionately even stricter, it entails control of normative choices based on technical and scientific data (knowledge). Legislative provision and scientific data become part of a "scientific adequacy scrutiny"[22], derived type of reasonableness scrutiny within scientific sphere. Having regard to the content (merit) of legislative choice, the Court

18 Spadaro, Ruggeri, *Lineamenti di giustizia costituzionale*, p. 107, according to whose this judgement have represented a turning point in the definition and conceptual position of reasonableness (Ibidem).

19 Chessa, *Bilanciamento ben temperato o sindacato esterno di ragionevolezza? Note sui diritti inviolabili come parametro del giudizio di costituzionalità*, in *Giurisprudenza costituzionale*, 1998, p. 3934.

20 Barile, *Il principio di ragionevolezza nella giurisprudenza della Corte costituzionale*, in Aa. Vv., *Il principio di ragionevolezza nella giurisprudenza della Corte costituzionale. Riferimenti comparatistici*, Giuffrè, 1994, pp. 21 ss.

21 Tallacchini, *La costruzione giuridica dei rischi e la partecipazione del pubblico alle decisioni science-based*, in Comandè, Ponzanelli (eds.), *Scienza e diritto nel prisma del diritto comparato*, Giappichelli, 2004, p. 339.

22 Gemma, *Giurisprudenza costituzionale e scienza medica*, in D'Aloia (ed), cit., p. 60.

affirms its own legitimacy to evaluate whether or not the scientific or technical references selected by the legislator are complying with a minimum standard of reasonableness, self-restraining in the meantime the scrutiny of the measure of legislative "scientific discretion" accordingly to the general prohibition to interfere with the discretionary content of legislative choices.

The scientific adequacy scrutiny seems to develop, therefore, a residual efficacy – as extrema ratio[23] – which can be applied only before a "redundant" scientific unreasonableness of legislative provisions, as manifestly pointed out by constitutional case-law.

In the light of demonstrating this assumption, it seems to be appropriate to make reference to the judgement no. 114/1998, in which the Court defines some binding criteria of "evaluative prudence". On the one hand, indeed, the Court declares its own legitimacy in fulfilling a scrutiny in case of a clash between science and norms[24], in the light of verifying whether the legislative choice has passed on what would be the confirmed scientific references or the strict link with the concrete situations which have been regulated. However, in the following part of its reasoning, the Court seems to operate a modulation of that "self-attributed" competency, in the part in which it stresses that to achieve an unconstitutionality declaration it is has to be proved that scientific data which the law is based on are undoubtedly erroneous or it reaches such a degree of vagueness to impede any possible rational application by the judge".

This attitude, provided by the Court in evaluating reasonable configuration of "legislative facts" and of causal relationship required by a law having as object medical-scientific matters, seems to make reference to the traditional coherence (or "evidence", according to Lavagna's theory) scrutiny of the laws, means of scrutiny in which constitutional judge makes reference to parameters exterior to the norms derived also from extra-normative data, in which technological and scientific knowledge can be appropriately included.

This decision-making approach is referable to the category of the scrutiny of both the norms' factual assumption (precondition) and legislative prognosis accuracy (Bin, p. 328), through which the Court verifies (checks) the plausibility of factual elements and the congruence of their interpretation provided by the legislator in the light of their normative utilization. This scrutiny becomes decisive within the scientific context, particularly when the legislative utilization of technological data is functional to regulate normative situations in which constitutional rights and goods are involved: the effectiveness of the protection of the fundamental rights at stake depends largely from the adequacy and congruity of the scientific data's evaluations provided by the legislator, becoming insofar crucial a constitutional (*ex post facto*) control by the Court on the scientific content of legislative choices.

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23 According to D'Amico, T*ecniche argomentative e questioni scientificamente controverse in materia di biodiritto: U.S: Supreme Court e Corte costituzionale a confronto*, preliminary version, in Forum Biodiritto, Trento, may, 28-29, 2008 (proceedings in printing), p. 26.

24 Scaccia, cit., p. 233.

As pointed out above, the constitutional Court has used prudently this dimension of reasonableness scrutiny. It recognizes a broad margin of legislative discretion in determining the most adequate scientific contents in the light of guarantee the achievement of legislative aims, declaring the unconstitutionality of a law exclusively whether the level of certainty of scientific data collected becomes so high to provoke the arbitrariness or the irrationality of the provisions object of the scrutiny (judgement no. 342/2006).

A "scientific reasonableness presumption" of legislative choices can be drawn, in all those cases in which scientific data don't arise a pervasive degree of scientific certainty with regard to the technical acquirements on which they are based. Nevertheless, this presumption has not to be considered as absolute: whether an increasing (enlargement) of legislative discretion in inverse proportion with scientific uncertainty degree of scientific data[25] is legitimate and even appropriate in the light of guarantee of legal certainty, otherwise this expansion cannot be unlimited, especially within the biomedical field, in which fundamental rights of involved individuals are reaching an ever increasing relevance.

However, it is required a minimum level of scientific reasonableness which must characterize the content of legislative choices, in the light of both the feasibility of factual elements itself and their consistency (congruence) with the legislative aims. From the legislator's viewpoint, it is not advisable to pass on the degree of uncertainty of scientific data at the beginning of law making process[26], because the uncertainty's degree – the entity of the scientific doubleness – constitutes both a condition of the legitimacy and a parameter to define the admitted (according to the constitutional case-law) dimension of *discretionary* legislative intervention. Accordingly, the Italian constitutional Court seems to consider the discretionary legislative intervention as a *surrogate* of scientific uncertainty.

Conclusively, for what concerns the scientific reasonableness scrutiny on the *content* of legislative choices, the constitutional scrutiny cannot involve an appreciation on the merit of feasibility of scientific data or technical applications, but it must be limited to an external scrutiny of the "non evident unreasonableness" of the legislative prognosis or of the technical evaluation transposed into the legislative regulation[27].

With regard to the scrutiny of legislative choices involving scientific data, the Court's attitude can be defined as *prudent*, because of it recognizes a wide degree of legislative discretion, on which the margin of appreciation of constitutional judges must be limited[28.] Therefore, whether a broad margin of technical and scientific evaluation has to be guaranteed to the legislator, consequently the

25 Luciani, *I fatti e la Corte: sugli accertamenti istruttori del giudice costituzionale nei giudizi sulle leggi*, in *Strumenti e tecniche di giudizio della Corte costituzionale. Atti del Convegno, Trieste, 26-28 maggio 1986*, Giuffrè, 1988, p. 545.

26 Cerri, *Diritto-scienza: indifferenza, interferenza, protezione, promozione, limitazione*, in Ponzanelli, Comandè (eds.), cit., p. 380.

27 Camerlengo, cit., p. 179.

28 Cerri, *Ragionevolezza*, p. 21, underlining that "estremamente limitato è il controllo della nostra Corte sulle valutazioni tecniche complesse ed opinabili".

constitutional Court must limit itself in sanctioning exclusively the evident and irrational lack of reception of new (on-going) relevant scientific acknowledgements within the law making process.
Nevertheless, whether the degree of intrusiveness of constitutional scrutiny into the legislative reception of scientific data is generally limited, what kind of attitude is the Court following with regard to the way through which scientific data have access into the law making *process*? The analytical perspective is moving from the scrutiny of the content of legislative choices within the medical-scientific ambit to a scrutiny of the decision making mechanisms adopted: the object of the scrutiny is therefore becoming "*how*" the choices are achieved more than "*what*" the choices consist in, the *quomodo* of the making process instead of the content of normative product.
In other terms, the "scientific reasonableness" scrutiny modifies – integrates – its own nature, becoming a means for evaluating the accuracy (procedural reasonableness) of the *decision making circuits* utilized to achieve the political decision[29] instead of a "mere" means for checking the constitutional legitimacy of the *content* of the provisions.

3. From the reasonableness of the content of legislative choices to the reasonableness of the methods of the choices. The paradigmatic case of judgement no. 282/2002 of Italian constitutional Court.

Even this evolution within the case-law of constitutional Court toward a scrutiny of the decision making mechanisms seems to be consonant with a traditional dimension of reasonableness. In fact, according to the judgement no. 53 of 1974, even whether the Court states that discretionary legislative choices cannot be challenged, a space open to a constitutional scrutiny nevertheless has to be recognized, in those cases in which an absolute vacuum of logic and coherent motivations is subsisting or an evident contradiction within the normative preconditions may affect directly the protection of constitutional rights (accordingly, judgement no. 14/1964). The reference to an evident contradiction on the premises of the political choices provided by the legislator seems to entail indirectly a concept of reasonableness intended as a means through which the facts have access into the legislative making process[30]. Accordingly, the reference to the facts – scientific data – can be considered a necessary (even compulsory) quality not only of the legislative product, but also of the law making process[31], requiring a constitutional scrutiny affecting also the legislative process.
Whether it is possible to determine a continuity within the constitutional case-law, the judgement no. 185 of 1998 (so called "Di Bella case") may be considered an effective qualitative change in the

29 Bin, p. 359, si riferisce al ruolo del giudice costituzionale nel garantire la regolarità *lato sensu* procedurale del processo politico, per sanare le conseguenze delle sue disfunzioni e ristabilire le garanzie costituzionali di una regolare immissione degli interessi nel processo decisionale.
30 Lorello, cit., p. 102.
31 Stone Sweet, *Proportionality Balancing and Global Constitutionalism*, draft paper, develops the need to incorporate proportionality standard into the legislative process.

traditional line of reasoning of the Court, because explicitly recognizes the essential relevance of scientific bodies in regulating scientific activity within the legislative making process. In this judgement the Court has explicitly stated a mutual relationship between legislative power and scientific expertise, which must be integrated into a shared decision making process characterized by both an heteronomous (legislative) and an autonomous (expertise) intervention. According to the Court, technical-scientific bodies must develop an essential relevance within the medical field – both in therapeutic and experimental activity – because their opinions are invested of a binding normative efficacy, representing an *extra-legem* regulatory means with a scientifically bound content excluded from the chance to be challenged before the constitutional Court. Insofar, the Court cannot substitute the opinions which – according to the quoted judgement – must be provided by recognized technical bodies with an own autonomous evaluation.

The continuity within the constitutional case-law even with regard to this matter has to be stressed. In fact, the Court has analogously applied to the regulatory power of technical bodies the principle according to which the *merit* of discretionary legislative choices cannot be challenged, coherently with an argumentative perspective which has been confirmed by the judgement no. 188/2000. In this judgement, the Court makes reference to a "*reserved competence"* of the technical-scientific bodies in determining the technical content of therapeutic activity (in the specific case, the list of tumorous diseases admitted to a free selling of the drugs), stressing at the same time the liability corresponding to these bodies. Therefore, the Court is enlarging the circuit*s* of legitimation of the political decision process towards a third legitimacy source, which goes to complete the *democratic* source (expressed by the Parliament) and the *constitutional* one (of which the constitutional Court is expression).

It could be possible identify an indirect compliance with a third legitimacy level of legislative decision making, which in constitutional judicial review gets to be an extra juridical evaluation standard. In fact, traditional binary legitimacy structure of law making based on mutual reciprocity (complementarity) between democratic *potestas* and constitutional *auctoritas*, is thrown into crisis and developed in a ternary sense because of a increasing need of data which exclusively the science can offer[32]. Policy making capability (*potestas*) and juridical power (*auctoritas*) are integrated by a further form of scientific *expertise*, which entails a crossroads – in the meaning of opportunity openness and strength constitutional enforce process chance – for the (apparently) consolidated system of law making procedure within constitutional state. Scientific method, referred to acquisition of scientific knowledge methodologies and the results deriving to ever-increasing scientific advancement, could be qualified as a requirement for the validity of the laws on scientifically controversial matters[33], according to a non-exclusive but integrated nature in regard to other law making process legitimacy

32 Spadaro, *Sulle tre forme di "legittimazione"*, in D'Aloia (ed.), cit., p. 574.

33 Ainis, *Politica e cultura*, p. 26.

sources.

Starting from this mutual complementarity between judicial review and scientific expertise, which excludes constitutional adjudication concerning scientific evaluations, it seems to be possible derive a further normative consequence, which involves legislative policy power (expression of *democratic* legitimacy of decision making process) and its relation with expertise (expression of *scientific* legitimacy of decision making process).

The (provisional) exit of this on-going changing of paradigm within the constitutional case-law in evaluating the reasonableness of the laws, due to a replacement of the viewpoint from the legislative act to the normative process, is represented by the judgement no. 282/2002[34], in which significantly the judgement no. 185/1998 has been quoted, indirectly stressing the continuity within the constitutional case-law. This judgement, concerning the legitimate margin to be recognized to the legislative intervention with regard to the merit of medical and therapeutic choices, has changed the object of reasonableness scrutiny from the content of the act to the modalities of the legislative process, recognizing the absolute relevance of the manners through which medical-scientific data have access in the legislative activity. This mutation of perspective develops a direct incidence not only on the political but also on the *procedural* discretion of the legislator, expressing a principle according to which when scientific data have access to the law making process, the resulting law cannot be exclusively expression of the mere discretionary power of the legislator[35].

Consequently, after have been stated that the general rule in this matter is constituted by the autonomy and the liability of the physician that, according to the patient's consent, performs own professional choices founding his decision on the available knowledge[36], constitutional judges specify that, although it has to be recognized a normative area characterized by a scientific expertise's prevalence and – as a consequence – that legislative intervention in this field must operate in a residual and exceptional way, it could not derive automatically that any legitimate chance of intervention must be denied to the legislator[37], ushering in this way a legitimacy clause for legislative power discretionary exercise.

In fact, the Court seems to "send" some methodological principles to the legislator, in order to assure a "scientifically oriented" exercise of legislative discretionary power in all whose cases in which a therapeutic or medical method is at stake. The Court has declared that a legislative intervention on the

34 The case 282/2002 of Italian Constitutional Court deals with the issue concerning fundamental principles in the field of health protection by the State, in the light of the reform introduced by constitutional law no. 3/2001. In said decision the Court, outlines a reconstruction of the constitutional balance of rights and interests in this field, providing for compulsory procedural suggestions in order to guide the legislative activity. The decision deals directly with therapeutic practices as well as the nature of its legislative regulation; nevertheless, it seems that, in its argumentation, the Court intends to extend its value perspective up to include the overall relation between science and law.

35 Camerlengo, cit., p. 172.

36 *«la regola di fondo in questa materia è costituita dalla autonomia e dalla responsabilità del medico che, sempre con il consenso del paziente, opera le scelte professionali basandosi sullo stato delle conoscenze a disposizione*».

37 «*la conseguenza che al legislatore sia senz'altro preclusa ogni possibilità di intervenire*».

merit of therapeutic choices related to their pertinence cannot derive from evaluations based exclusively on the mere political discretion of the legislator, but the legislator must provide for the elaboration of opinions (advice) based on the check of the level of the acquired scientific knowledge and experimental evidence, by means of scientific – national and international – institutions, considering the "*crucial relevance*" which has to be recognized to the technical-scientific bodies. In any case, according to the Court, the legislative intervention must be the *result* of this kind of (previous, within legislative process) check[38].

Thereby, the exercise of legislative discretion power could not be totally excluded, also considering the intrinsic uncertainty related to the relativity of scientific knowledge, but – according to the judgement no. 282/2002 – it suffers a pollution coming from the scientific evaluations provided by technical bodies. This "*scientific pollution*" increases its incidence in a way progressively opposite to the level of scientific uncertainty, orienting the discretionary legislative choices, also in the matter of the normative way chosen to select the scientific and therapeutic instruments which effectively guarantee the rights involved in each concrete case.

Essential elements for a new decision making procedural theory are contained in the reasoning of the Court, in matters characterized by an high level of scientific criticism, such as in the field of therapeutic scientific research and experimentation. According to the Court, in this matter, a legislative exogenous intervention must be *proportional* to the protection of the constitutional rights involved and *adequate* to the public utilities pursued, according to a "traditional" application of the reasonableness principle[39]. It seems therefore to be corroborated the application of a further dimension of the reasonableness. The reasonableness, in this specific issue "science involved", must be intended as an interpretative instrument which consents an inner control within the legislative choices, related to the parameters (coherence, reasonableness, consistency with the aims) which the legislator must in any case fulfil in achieving its choices[40]: again, reasonableness is acting with regards to the *method* by which legislative choices are carried out.

As it has been mentioned above, the traditional conceptual area of this principle seems to be extended also to the concrete modalities through which legislative power determines its normative choices,

38 «*un intervento sul merito delle scelte terapeutiche in relazione alla loro appropriatezza non potrebbe nascere da valutazioni di pura discrezionalità politica dello stesso legislatore, bensì dovrebbe prevedere l'elaborazione di indirizzi fondati sulla verifica dello stato delle conoscenze scientifiche e delle evidenze sperimentali acquisite, tramite istituzioni e organismi – di norma nazionali o sovranazionali – a ciò deputati, dato l'"essenziale rilievo" che, a questi fini, rivestono gli organi tecnico-scientifici; o comunque dovrebbe costituire il risultato di una siffatta verifica*».

39 The constitutional Court expressly specifies the constitutional foundation which legitimates procedural modalities indication, ratifying a necessary connexion between rights to effective cares and to be respected as person, linking both to article 32, second paragraph, of Italian Constitution, and therapeutic practice: right to health and to physical and psychological integrity are interpreted as applicability condition of procedural model designed by constitutional judges, through which can be guaranteed the *appropriateness* of normative contain (and of therapeutic choices) and compliance of necessary precautions.

40 Bin, *Diritti e argomenti*, Giuffrè, 1992, p. 63, footnote 157 («*controllo (...) "interno" alle scelte legislative, relativo ai canoni (di coerenza, ragionevolezza, congruità rispetto al fine) che il legislatore deve comunque rispettare nel compiere le sue scelte, quali esse siano*»).

recognizing a further level of reasonableness not only referred to the content – and to its compatibility with constitutional system – but also to the normative process. Accordingly, the law making procedure must be related with parameters which are deductible from a so-called "scientifically intended constitution", based on recognizing a plural nature of regulatory legitimacy, founded as on the scientific and rational progress (scientific legitimacy, procedurally oriented) as well as on a system of constitutional values (constitutional legitimacy)[41].

The Court seems to indicate to the legislator some *methodological suggestions* in order to guarantee a lawful use of legislative discretion, with regard to the controversial scientific issues. It has been proposed, although not explicitly, a *scientific reasonableness principle*, according to which the legislator *ex se* – as a political subject - cannot interfere into the concrete therapeutic choices except when it is guided by the opinions provided by scientific bodies and not exclusively by its own political discretion[42]. In this regard, from the decision no. 282 it can be derived an implicit, such as a formal condition of constitutional legitimacy, procedural burden for the legislator, which cannot leave aside a broad and reliable reconstruction of the facts which the legislative regulation will bear on[43]. In this area, according to the Court, it has to be considered compulsory an adequate system of specialized technical acknowledgement to adopt legislative measures binding the healthcare professionals. In contexts characterized by an high level of scientific uncertainty, the legislative decision margins must be wider, balancing the factual uncertainty with an artificial certainty derived from the legislative regulation, which suffers an increasing compression directly proportional to the development of the acquisition of scientific knowledge.

Therefore, even if, according to the Court, constitutional rights or duty are at stake or a situation of scientific uncertainty may allow – and also impose – a legislative intervention in regulating the concrete therapeutic (and experimental) methods, this intervention must be founded on revised acquisitions of scientific knowledge. This multilevel normative system must be interpreted in a dialectic and harmonic sense, according to a growing gradualism of legislative incidence linked with the level of scientific uncertainty, whereby when there is a clash among scientific and legal evaluations, due to the fact that science can achieve only transitional outcomes, the law always has to prevail on the existing scientific evaluation. This prevalence would be determined because only the legislative intervention is able to guarantee (even if often through *fictiones iuris*) the certainty of the law[44].

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41 Spadaro, *Cellule staminali e fecondazione assistita: i dubbi di un giurista*, cit., p. 4.

42 Bin, *La Corte e la scienza*, in D'Aloia (ed.), cit., p. 9 («*è proibito al legislatore in sé, quale soggetto politico, di intervenire nelle scelte terapeutiche se non quando a guidarlo siano, non la "discrezionalità politica", ma motivazioni fornite dagli organismi tecnico-scientifici*»).

43 Camerlengo, *Indizi di perdurante asimmetria tra legge statale e legge regionale. La primazia delle valutazioni scientifiche*, in *Le Istituzioni del Federalismo*, 2002, p. 697, («*non può prescindere da una compiuta e attendibile ricostruzione dei fatti su cui la disciplina così prodotta è destinata ad incidere*»).

44 According to Salmoni, *Le norme tecniche*, Giuffrè, 2001, p. 114, that mentions Violini, *Sui contrasti tra valutazioni*

Therefore, the "uncertainty principle" rules the attitude of the law with regard to scientific data and this condition restrains the legislator, imposing a duty to react against the risk which uncertainty provokes[45], a kind of duty of legislative intervention. But even when a legislative active intervention is admitted and also required, it is necessary to identify – according to the Court – some correctives, as well as procedural guarantees, to prevent a sort of degeneration, by which an ordered normative crystallization (certainty) could lead towards a formal "legislative petrification" (paralysis), when it does not recognize and include necessary cognitive contribution (expertise) of scientific community into the normative process[46].

The reference of the judgement, when the right to health is involved, to a necessary control of the state of scientific knowledge and experimental evidences gained through specialized bodies and institutions[47], seems to be in accordance with this integrated normative system. According to the Court, legislative product must represent a derivation – the outcome of this control, quoting the Court – from this advisory and cognitive activity of the committees. So, the legislative product, which is directed to determine the pertinence of therapeutic cares, cannot be constituted by evaluations founded exclusively on the political discretion, but by the elaboration of guidelines («*indirizzi*») based on the data acquired from the advisory participation of institutions and boards, national and international, to which it must be recognized an essential relevance in this matter: relevance which expresses itself, as indirectly, through an advising activity to ensure solid scientific legitimacy foundations for discretionary legislative evaluations; as directly, through a protection of involved fundamental rights based on medical *deontological* rules application, effective application of which is supervised for medical representative organs.

It can be derived some suggestions on the legislative method, which transcends the concrete legal case, assuming a general relevance, even if in the specific "therapeutic practice" area. A relevance, through which the constitutional Court recognizes, under prescriptive terms (according to the Court, «any intervention on the merit of therapeutic choices may provide the elaboration of guidelines»), the need of a control of the state of scientific knowledge and experimental evidences gained through specialized bodies and institutions: a verify, which seems to be previous to and to be considered as element, even condition, of the legislative decision, which may however constitute the outcome of that

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giuridiche e valutazioni scientifiche nella qualificazione della fattispecie normativa: la Corte compone il dissidio ma non innova l'approccio, in *Giurisprudenza costituzionale*, 1998, p. 975 («*quando tra valutazioni giuridiche e valutazioni scientifiche vi è un contrasto, originato dalla circostanza che la scienza non conosce che risultati transitori (...), è sempre il diritto che deve prevalere sulla valutazione scientifica ad essa sottostante*»).

45 Bin, La Corte e la scienza, p. 6.

46 Not even legislative paradigm can assure an absolute normative certainty, because of "an intrinsic penumbra of uncertainty" which characterizes legal rules (Hart, *The Concept of Law*, 1961). Moreover, there is a structural lack into the legislative means: in fact, "it is impossible to draft legislation with sufficient precision and clarity that addresses every possible future technical variation", quoting Bennett Moses, *Understanding Legal Responses to Technological Variation of In Vitro Fertilization*, in *Minnesota Journal of Law, Science and Technology*, 6, 2005, p. 578.

47 «*verifica dello stato delle conoscenze scientifiche e delle evidenze sperimentali acquisite tramite istituzioni e organismi (...) a ciò deputati*».

preliminary verify.

The constitutional Court's argumentative path takes on a peculiar meaning, not only in redefining the competence allocation between State and Regions, but also to propose a very strict redefinition of the legislative power *tout court*, apart from the political authority of which is expression[48]. It seems to be possible to make reference to a bright boundary drowned by the Court between medical and legislative activities, through the application a scientific dimension of reasonableness both in a substantial and procedural perspective, for identifying a "restricted area" for legislative activity, out of which the legislator generally could not intervene unless other constitutional rights or interests have to be protected. In any case, the legislative intervention will be only *eventual* and *subsidiary,* compared with the concrete choices which are expression of the decisional autonomy of the subjects involved into the therapeutic decision[49].

To summarize, even when the legislator may intervene, the result of its normative activity must be based on evidence and expertise derived from scientific bodies recognized by "scientific community", to achieve a flexible and adaptable law: a prospective, "homoeostatic law"[50], able to adapt itself to the ongoing development of technological knowledge, regarding to which reasonableness must act as measure of lawful (proper) exercise of legislative power. This is the outcome clearly expressed by the ruling of the Court, in which the unconstitutionality of the regional law has been declared on the ground that regional intervention is not founded nor it want to be founded on technical-scientific acquisitions checked by qualified bodies, but it arises on the contrary an autonomous legislative choice, expressly intended as a precautionary means[51], looking forward to coming (and unspecified) verifications (point 6, "Considerato in diritto").

4. Replacing the boundaries: from a pathological to a physiological perspective of the reasonableness criterion within the legislative process.

The change – the harmonic development – within the content and the aims of the reasonableness scrutiny seems to produce the necessity of a re-thinking of the concrete modalities of the legislative making process, with regard to scientific and medical regulation. The overall legislative process becomes a direct object of the constitutional adjudication, through a "scientific reasonableness" scrutiny, enlarging the traditional target constituted by the product of this process, the legislative provisions contained into a statutory law. This development has to be considered more as an additional

48 «*ridefinizione molto restrittiva dei poteri legislativi tout court, di qualsiasi autorità politica siano espressione*».

49 Violini, *La tutela della salute e i limiti al potere di legiferare: sull'incostituzionalità di una legge regionale che vieta specifici interventi terapeutici senza adeguata istruttoria tecnico-scientifica*, in *Le Regioni*, 6, 2002, p. 1456.

50 Rodotà, *Diritto, scienza, tecnologia: modelli e scelte di regolamentazione*, in Comandè, Ponzanelli (eds.), cit., p. 409.

51 About the precautionary principle as intended by the decision 282/2002, from a critical perspective, Meola, *La regolamentazione giuridica delle biotecnologie: la dimensione dei rapporti tra tecnica e diritto nel contributo della giurisprudenza costituzionale*, in *Rassegna di diritto pubblico europeo*, 1, 2005, pp. 162 ss.

more than a substitutive activity: the scrutiny of the concrete methods and means of the legislative making process goes to enlarge – not to substitute – the scrutiny of the legislative provisions. The change is focused in the viewpoint chosen by the Italian constitutional Court, which seems to interpret the reasonableness principle not only as a technique through which check the lack of a minimum standard of adequacy, proportionality and necessity of the content of legislative choices, but also as a necessary condition within the legislative process, useful to guarantee the fulfilment of these standards by the legislative product.

In other terms, the application within the legislative making process of the methodological suggestions provided by the judgement no. 282/2002 seems to constitute a (even if relative and not absolute) presumption of the "scientific reasonableness" of the legislative product. These methodological "warnings", by limiting the degree of the discretionary exercise of the legislative power, contribute paradoxically to increase the level of both the legitimacy and the (scientific) grounding of the legislative choices. The scientific dimension of reasonableness principle therefore could play an essential role not only in the pathological stage before the constitutional Court, but also within the physiological dimension of the law making process. The reasonableness principle seems to change (enlarge) its nature evolving from a traditional nature of *marker* ex post of the malfunctioning of the legal order within the judiciary (ordinary and constitutional) activity, to a new (even if entrenched in the consolidated constitutional case-law, see judgement no. 1130/1988) function, which expresses itself ex ante, within the normative process, as a condition for the achievement of a balanced relationship between the facts and the law, considering the facts as a required element within the construction of the normative regulation[52].

The centrality of normative process emerges, regarding which is setted up the necessity of spaces and mechanisms opened to expertise and scientific knowledge, though considering their intrinsic relative nature. It is configured a participative, circular and continuous process, basing its legitimacy on a previous legislative recognition: a 'soft law' characterized by flexibility and openness principles, historically conditioned by specific temporal validity clauses, transposing in juridical context the "relative scientific uncertainty" principle, which affords to ensure legal effectiveness recognizing its intrinsic relative nature.

This argumentative approach cannot be considered as an exception within the constitutional case-law: successively, the constitutional Court has applied the same methodological perspective – in the judgements no. 338/2003, 16/2004, 116/2006 – stressing the para-legislative criteria according to which the border between allowed and not allowed therapies, based on scientific and experimental acquisitions, concerning directly and compulsorily the fundamental principles in this matter, cannot be based exclusively on the mere political discretion of the legislator (no. 338/2003); accordingly, and

52 Lorello, cit., p. 103.

analogically, even the determination of restrictions against the freedom of private enterprise in this field, based on precautionary principle in the interest of the human health protection, can be constitutionally justified exclusively whether are based on specific guidelines provided by scientific international recognized bodies (no. 116/2006).

This further and broader application could demonstrate an on-going consolidation of a "scientific dimension" for the reasonableness principle, strictly related with the link between the concrete characteristics of the law making process and the normative quality of the legislative product. Within the medical-therapeutic field, a reasonable law making process, directed to guarantee the effectiveness and the concrete compliance of the law, has to become means and method for a dialectical "dialogue" between conflicting stakeholders, ensuring the transparency of the procedure and the participation of the expertise[53]. Participation and transparency as expression of the reasonableness principle within the legislative making process cannot be considered as self-referential values: on the contrary, they express a functional nature, permitting a consensus recovery based on *equity* in the relationship between all parties involved (for instance, through a real effectiveness of informed consent instead of its formal automatism) and not only on a decision bargaining; finally, a renewed legislative process conception, which permit to foresee in a *physiological* level of guarantee (normative protection of fundamental rights) the effectiveness recovery which actually takes place in a pathological level through the remedies provided by the constitutional adjudication.

Potential criticisms related to this changing of the scrutiny's "target" from the content to the method of the making process could be identified in the low references which constitutional Court usually makes to the preparatory acts within legislative making process to define the legislative purposes. This could impede a concrete chance to check the methods and the procedural criteria (participation of stakeholders, hearings of expertise and transparency) followed by the legislator. Anyway, it could be possible hypothesize a deductive derivation of relevant indicators from the content – the text – of the legislative product, useful to verify the procedural (and scientific) reasonableness of the making process. Again, from the content to the method of legislative choices, in a circular and continuous interpretative circle within which both – substantial content and procedural method – are mutually conditioned: a soft legislation, functional to be concretely assumed and effectively applied by the involved subjects, characterized by general guidelines, reference to the level of certainty of scientific acquisitions, "sunset rules" (Rodotà) and remands to technical norms and rules, can be achieved exclusively through a law making process within which the expertise is considered as an extra-juridical source of the juridical (legislative) sources[54].

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53 Ortino, *From 'Non-Discrimination' to 'Reasonableness': a Paradigm Shift in International Economic Law?*, in *Jean Monnet Working Paper*, 1, 2005, makes reference to a "procedural reasonableness" concept.

54 Casonato, *Introduzione al biodiritto. La bioetica nel diritto costituzionale comparato*, Università degli Studi di Trento, 2006, p. 212.