

JUDGMENT NO. 107 YEAR 2012

In this case the Court considered a referral from a court hearing proceedings against a regional health minister, brought by the parents of a child who had been harmed following the administration of the MMR vaccine, which is recommended but not mandatory. Whilst the legislation provided for the payment of compensation in the event of injury caused as a result of mandatory vaccination, no such provision was made in relation to that resulting from non-mandatory but recommended vaccinations. The Court accepted the application, ruling that the right to compensation arose not out of the mandatory nature of the vaccination, but rather the duty arising on the grounds of solidarity towards those who, in consenting to non-mandatory vaccination, pursued an interest of society as a whole: “the decisive reason for the right to compensation is the collective interest in health and not the mandatory status as such of the treatment, which is simply the instrument for pursuing that interest”.

(omitted)

THE CONSTITUTIONAL COURT

(omitted)

gives the following

JUDGMENT

in proceedings concerning the constitutionality of Article 1(1) of Law no. 210 of 25 February 1992 (Compensation for individuals harmed by irreversible complications resulting from compulsory vaccinations, transfusions and the administration of blood derivatives) initiated by the *Tribunale ordinario di Ancona* in relation to the proceedings pending between C. P. and L. E., acting in their capacity as the parents of L.G., and the Minister

for Employment, Health and Social Policies of Marche Region by referral order of 21 December 2010, registered as no. 214 in the Register of Orders 2011 and published in the Official Journal of the Italian Republic no. 44, first special series 2011.

Having heard the Judge Rapporteur Paolo Grossi in chambers on 7 March 2012.

(omitted)

Conclusions on points of law

1.— The *Tribunale ordinario di Ancona* raised, with reference to Articles 2, 3 and 32 of the Constitution, a question concerning the constitutionality of Article 1(1) of Law no. 210 of 23 February 1992 (Compensation for individuals harmed by irreversible complications resulting from compulsory vaccinations, transfusions and the administration of blood derivatives), “insofar as it does not provide that the right to compensation established and governed by the said Law also be available under the conditions set forth thereunder to individuals who have suffered injury and/or illness which has resulted in irreversible damage to their physical and psychological integrity due to their subjection to non-mandatory but recommended vaccination against measles, mumps and rubella”.

The referring court states that it was requested to rule, as an employment court, on the application – seeking compensation under the terms of the contested legislation – filed by the parents of a child who had contracted serious illnesses deemed to fall under Category VII of Table A annexed to Presidential Decree no. 834 of 30 December 1981 (Definitive reorganisation of war pensions, pursuant to the authorisation laid down by Article 1 of Law no. 533 of 23 September 1981) following vaccination against measles, mumps

and rubella (MMR) with a vaccine which was subsequently withdrawn from the market a few days after administration. Whilst the vaccination was not mandatory – and thus not capable of establishing entitlement to the compensation provided for thereunder in the event of complications pursuant to the contested legislation – it was nonetheless strongly recommended by the public authorities, and had been the object of an intense awareness-raising campaign, as is demonstrated by the numerous documents issued in that regard by the public administration. Accordingly, it was claimed to concern the same principles according to which this Court has previously ruled that the compensation provided for under the contested legislation may be extended to classes of individual which have suffered injury as a result of vaccinations made at a time when they were not yet mandatory, but only recommended. The lower court continued that this should be ordered owing to the adequate prominence which must be afforded to the principle of solidarity, according to which society must take responsibility, through specific compensation, for the injuries suffered by individuals where they subject themselves to treatment with a view to the protection not only of individual health but also of public health.

This is alleged first and foremost to have resulted in a violation of Article 2 of the Constitution, in that legislation which does not provide that individuals, such as the daughter of the applicants, who have suffered irreversible harm as a result of vaccinations recommended under a health policy due to requirements to protect the health of society at large – as the vaccination against measles, mumps and rubella has been demonstrated to be – are to be regarded as beneficiaries of the right lacks coherence. Article 3 of the Constitution is also alleged to have been violated in that if no fair redress were available to the recipient of the recommended treatment, this would have the irrational result of allowing compensation to those whose parents who behaved in a manner compatible with general utility where threatened by a

sanction, whilst on the contrary denying it to those whose parents decided to vaccinate their children on the grounds of solidarity. Finally, Article 32 of the Constitution is also claimed to have been violated, since the guarantee of the right to health of vaccinated individuals who, having accepted the vaccination in the name of solidarity towards others and the bonds which tie them to society at large, subsequently suffer irreversible harm to their health in parallel with a benefit expected for society at large would be unjustifiably thwarted.

2.— The question is well founded.

3.— This Court has taken the opportunity to assert in relation to mandatory or recommended vaccinations, and the right to compensation for damage to health following such treatment, since judgment no. 307 of 1990 – issued in relation to anti-polio vaccination for children aged under one, which was mandatory at the time – that “the law requiring healthcare treatment is not incompatible with Article 32 of the Constitution if the treatment is intended not only to improve or preserve the state of health of those to whom it is administered but also to preserve the state of health of others, as it is precisely that additional purpose, relating to health as an interest of society at large, which justifies the restriction on the individual right to self determination which is inherent within the right of each to health as a fundamental right”.

However, whilst “the constitutional significance of health as an interest of society at large” requires that “each individual may be obliged, thereby lawfully limiting his self determination, to undergo particular treatment in the name of that purpose, and hence of solidarity to others, even if this entails a specific risk”, it nonetheless “does not postulate the sacrifice of the health of an individual in order to protect the health of others”. It follows that “a correct balancing between the two aforementioned dimensions to the value of health – and the very same spirit of solidarity (which must obviously be considered to be reciprocal) between the individual and society at large which lies at the

basis of healthcare – implies that, should such a risk manifest itself, further protection should be afforded to the individual who has received treatment. In particular, the minimum content of the right to health which is guaranteed to him would end up being sacrificed were he not in any case to be assured the remedy of fair redress for the harm suffered from society at large, and on its behalf from the state which ordered the mandatory treatment”.

As is known, the judgment referred to provided the basis upon which Law no. 210 of 1992 would be approved shortly afterwards (see the report on bill no. 4964 tabled in the Chamber of Deputies on 12 July 1990 which was included, along with other parliamentary initiatives, in the *travaux préparatoires* for the Law under examination), following which – based on the fixed premise that vaccination cannot under any circumstances be classified “as forced treatment” (judgment no. 132 of 1992) – not only was the close correlation within “constitutional law on health” between the fundamental right of the individual (the “individual and subjective” side) and the interest of society at large (the “social and objective” side) (judgment no. 118 of 1996) gradually established, but rather above all the need that, where the values in question come into conflict, the risk associated with a treatment which “sacrifices” individual freedom be accepted on the basis of solidarity.

Moreover, with the goal of establishing the principle that compensation should be paid in all circumstances in which the individual has exposed his health to risk in order to protect a collective interest, it was subsequently asserted that Articles 2 and 32 of the Constitution establish the obligation, which applies in parallel for the public at large, “to share, where possible, the burden of any adverse consequences” (judgment no. 27 of 1998). It was inferred from this that there is accordingly no reason to differentiate between a case in which “the treatment is imposed by law” and that “in which it is promoted by the public authorities according to law with a view to its widespread dissemination throughout society – i.e. to differentiate between a

case in which free individual self determination is annulled through the imposition of a penalty and that in which the state calls for cooperation by individuals in a health policy programme". It was specified that "a differentiation which denied the right to compensation in the latter case would constitute a clear irrationality within the law. In fact, it would treat those who were induced to follow a course of action of general utility on the grounds of social solidarity less favourably compared to those who acted under the threat of a penalty" (judgment no. 27 of 1998).

In summary, it follows that "the decisive reason for the right to compensation" is "the collective interest in health" and not "the mandatory status as such of the treatment, which is simply the instrument for pursuing that interest"; moreover, that interest acts as the foundation for the general duty of solidarity towards those who suffer harm after subjecting themselves to treatment (judgments no. 226 and no. 423 of 2000).

4.— On this basis it may be observed, more specifically, that whilst preventive action aimed at averting and containing the risk of contagion appears to be paramount in the fight against infectious diseases, the significance taken on by awareness-raising campaigns conducted by the competent public authorities with the purpose of reaching out to and involving as broad a segment of the population as possible is in any case decisive. Within this perspective – where it is even difficult to delineate with precision a "public" space for assessment and debate (which may be attributable to a collective body) as against a "private" space of choice (which may be attributable to individuals) – the various actors end up furthering an objective interest – that of wide-scale immunisation against the risk of contracting disease – irrespective of their specific intention to cooperate: it is entirely irrelevant, or indifferent, whether the cooperative effect is attributable in active terms to an obligation, or to persuasion, or by contrast in passive terms to the desire to avoid a sanction, or to take up an invitation.

Given the existence of various repeated campaigns promoting vaccinations, it is in fact natural for a general climate of “confidence” to develop in relation to “recommendations”: this means that, leaving aside the specific motivations of individuals, their choice to vaccinate themselves is in itself objectively aimed at safeguarding also the collective interest.

In parallel with this kind of involuntary cooperation in pursuing an objectively common interest – i.e. an authentically public interest – it will be natural to conclude that bonds which are strictly speaking rooted in solidarity may be created between society at large and individuals in the sense – above all – that the affairs of individual people must inevitably be considered also from an “overarching” perspective, that is one which relates to the entire community: this means, amongst other things, that where adverse events occur or permanent complications arise due to vaccinations conducted subject to the limits and according to the arrangements stipulated under applicable procedures, it must in fact be society at large that takes on the burden of the individual harm, and the individuals who have been injured should not be required to bear the cost of the collective benefit.

With regard to the values guaranteed under Articles 2 and 32 of the Constitution, the eclipsing – in other words – of the significance of strictly subjective motivations (which may have induced the individual to make choices required or recommended by the health authorities) justifies the transfer of the burden of any resulting harmful effects to society at large (which is also objectively favoured by those choices).

Moreover, within a context of non-negotiable solidarity, the level of compensation appears in itself to be aimed not so much at repairing unlawful harm (as damages), but rather at compensating the individual sacrifice which is deemed to correspond to a collective benefit: in fact, it would be unreasonable were society at large, acting through the competent bodies, to be able to impose or even recommend conduct aimed at protecting public health

without in return being required to answer for the detrimental consequences to the health of those who acted upon those requirements or recommendations.

Within a reference framework such as that referred to above, it is easy to discern how the practice of vaccination against measles, mumps and rubella has for more than a decade been the object of broad and insistent campaigns, including extraordinary campaigns, providing information and recommendations authorised by the highest levels of the public health authorities (involving the distribution of specific information both amongst healthcare professionals and with the general public), so much so that the official website of the Ministry of Justice still lists that at issue in the present case under its “recommended vaccinations”, in line with the decision adopted in the Ministerial Decree of 7 April 1999 (New calendar of mandatory and recommended vaccinations for children), Circular no. 12 of 13 July 1999 (Control and eradication of measles, mumps and rubella through vaccination), the National Plan for the Eradication of Congenital Measles and Rubella (approved for the 2003-2007 period by the State-Regions Assembly on 13 November 2003 and currently, for the 2010-2015 period, under the State-Regions Agreement of 23 March 2011) and the National Vaccines Plan (2005 update). The findings made on this matter by the referring court must therefore be deemed to be exhaustive for the purposes of validating the argument that, whilst the practice in question is not mandatory by law, it forms part of a body of healthcare protocols in relation to which the initiatives aimed at awareness-raising, the provision of information and persuasion adopted by the public authorities – which complies moreover with the “information projects” provided for under Article 7 of Law no. 210 of 1992 which are reserved to local health authorities “for the purposes of the prevention of complications caused by vaccinations” and in any case with the purpose of “ensuring the provision of correct information on the use of

vaccines” – are considered to be more appropriate and to better further the goal of protecting public health than mandatory vaccination.

ON THOSE GROUNDS

THE CONSTITUTIONAL COURT

rules that Article 1(1) of Law no. 210 of 25 February 1992 (Compensation for individuals harmed by irreversible complications resulting from compulsory vaccinations, transfusions and the administration of blood derivatives) is unconstitutional insofar as it does not make provision for the right to compensation, under the conditions and according to the procedures laid down by the said Law, for those who have suffered the consequences referred to under Article 1(1) following vaccination against measles, mumps and rubella.

Decided in Rome at the seat of the Constitutional Court, *Palazzo della Consulta*, on 16 April 2012.

(omitted)