A. 891. XXXVIII - "Multiple Sclerosis Association of Salta v. Ministry of Health – National State on *amparo* action - injunctive relief" - CSJN - 18/12/2003

Supreme Court:

-I-

At pages 390-397 of the principal file, the Federal Court of Appeals of Salta upheld the lower court's ruling that sustained the special *amparo* petition filed by the Multiple Sclerosis Association of Salta in which it declared null Resolution 1/01 of the National Ministry of Health – amending the similar 939/00 Obligatory Medical Program – regarding medication for sufferers of multiple sclerosis and isolated demyelinating syndrome, which excluded the treatment therein prescribed to those people who, in Salta Province, suffer from multiple sclerosis but who have not had two outbreaks or exacerbations in the last two years, or suffer from isolated demyelinating syndrome with a high risk of conversion to definite multiple sclerosis, without prejudice to the measures that the national administration may adopt to verify the certainty of the ailments.

Similarly, it upheld the ruling regarding the intervention of the Public Defender but revoked it with respect to the Multiple Sclerosis Associations of La Pampa, Mendoza, Corrientes, Santa Cruz and the Multiple Sclerosis Association of Argentina.

- II-

Disagreeing with the judgment, the representative of the National Ministry of Health lodged the special petition of pages 401-414, which was conceded with regard to the interpretation of federal regulations but denied with respect to the allegation of arbitrariness (pgs. 449-450), which led to the filing of the present complaint. The complaint asserted that the higher court incorrectly applied the resolutions that contain and approve the Obligatory Medical Plan by partially considering the contributed medical report as proof and arriving, therefore, at conclusions that lacked scientific rigor. The complaint stated that the verdict was purely arbitrary and dogmatic, at the same time that its premise was doubtful and self-contradictory. Regarding these points, it said that the lower court erred when it ruled that not providing the specified medication at a stage of the illness limits the right to the

protection of health, as said guarantee actually protects the ability to decline authorization of unnecessary treatments when there is no accurate diagnosis. The complaint claimed that the decision was arbitrary because not only did it accede to the claims of an illegitimate association but it further concluded that it had not received proof of the existence of an individual case that fit within the questioned measure. In sum, the complaint asserted that the tribunal nullified the state act even though the grievance was neither concrete nor actual, but merely conjectural.

In the same vein, it maintained that the *amparo* action was inadmissible, reiterating not only the inexistence of a concrete case but also explaining the impossibility for the judges to decide abstract questions, as they must decide the application of a law to a case or a matter in litigation. It further provided that for an *amparo* action to be viable, the disturbance to constitutional law must be strong and concrete and should remain outside the scope of questions of opinion, as is, in its criteria, that of the lower court; it equated this principle with the Supreme Court doctrine that determines the inadmissibility of a matter or case when a generic and direct declaration of unconstitutionality of an act of another branch is secured. On a separate matter, it attacks the Public Defender's legal standing based on judicial precedents that limit, it said, the Public Defender's performance when the subjective rights of the affected have been able to attain judicial protection, as occurred, in its understanding, in this litigation, where different associations submitted pleadings to this end.

-III-

The Federal Public Defender lodged, at pages 415-429, a special petition while the Multiple Sclerosis Associations of La Pampa, Mendoza and Corrientes and the Multiple Sclerosis Association of Argentina each filed applications for inclusion in the premises of the petition (pgs. 430-433). The petitions were accepted as a federal question but denied in regards to the charge of arbitrariness due to the appropriate complaints not having been filed. The Public Defender limited the object of the petition to the scope of the holding by indicating that it must have an *erga omnes* effect. This is so, in its view, because the Ombudsman acts in representation of the entire universe of those suffering from multiple sclerosis and

isolated demyelinating syndrome, and the opposite would violate the constitutional requirements that authorize its procedural participation (Arts. 43 and 86).

Similarly, it attributed the quality of the overall impact to the decision-making in all the processes in which that institution acts due to its national character and it believed the high court erred when it added collective protection to the jurisdiction of the intervening tribunal. It asserted, therefore, that recognizing the legitimacy of the guardian but making the decision only effective for the ill of Salta Province was contradictory.

It argued, in this vein, that those people who did not feel represented by the Federal Public Defender, individually or collectively, should initiate a lawsuit or present themselves in the already commenced suit and request a new judgment or that the judgment have no effect on them.

-IV-

Prior to any other analysis, it is appropriate to address the theme of formal admissibility of the special petitions initiated in the case by the Multiple Sclerosis Associations of Pampa, Mendoza and Corrientes and the Multiple Sclerosis Association of Argentina. In this regard, it is easy to see that the petitions are limited to an approval of the arguments outlined in the Federal Public Defender's appeal, and since the High Court's jurisprudence has noted the inappropriateness of the approval of the special petition (Judgments: 209:28, p. 70 and its citations; 257:48; 322:523), one must conclude that those appeals were incorrectly accepted by the lower court.

-V-

I believe that a logical evaluation requires analyzing the question that the State formulates regarding the right of the Multiple Sclerosis Association of Salta and the Federal Public Defender to bring the present *amparo* petition, because while the grievances demonstrated in this case are brief and have little basis, the existence of said presupposition constitutes an unavoidable requisite for the existence of a "case" or "controversy" that authorizes the intervention of a judicial tribunal (Ar. 116 of the Fundamental Law), as national justice does not come on its own initiative and only exercises jurisdiction over contentious cases at

the request of a party (Art. 2 Law 27) and its absence would render the consideration of the appellant's arguments futile (arg. Judgments: 322:528). One of the Court's constant jurisprudential concepts, based on that established in Arts. 116 and 117 of the National Constitution, expresses that justiciable cases pursue a concrete determination of the law between adverse parties, and thus there is no case "when a general and direct declaration of unconstitutionality of the regulations or acts of the other powers is made", nor, therefore, does any power exist in the Federal Judicial Branch that authorizes it, under such circumstances, to make declarations (Judgments: 307:2384, among others). In this manner, with respect to the standing of the plaintiff association, I repeat here the opinion given by this Attorney General on 22 February 1999 in "Asociación Benghalensis, *et. al* v. Ministry of Health and Social Welfare (Federal) on *amparo* Law 16.986", to whose terms Your Excellency referred arising from Judgments 323:1339. That is how I consider it, as long as the Multiple Sclerosis Association of Salta bases its legal standing to bring a case on the fact that it is holder of a collective impact right to the protection of health – in this case, the defense of the rights of people with multiple sclerosis – as part of the association's objectives.

Nevertheless, as the Tribunal stated in the precedent Judgments: 323:4098 with respect to the standing of the Federal Public Defender, while Art. 86 of the Magna Carta prescribes that that body has procedural standing, this does not mean that the judges should not examine, in each case, whether it is appropriate to designate the Public Defender holder of the substantive legal relationship on which the claim is based, as is required in all judicial processes (Court Reports: 323:4098 and its citations of Judgments: 310:2943; 311:2725; 318:1323).

Your Excellency held that Law 24.284 expressly excludes, from the area of competence of the body in question, the Judicial Branch (Art. 16, second paragraph) and establishes that if initiated its performance "interjects for the interested party an administrative resource or judicial action, the public defender must suspend its intervention (Art. 21) (Judgments: 321:1352). In the case at hand, various local multiple sclerosis associations have appeared in the case – without prejudice to that sustained about them in ap. IV precedent – and it is

the Multiple Sclerosis Association of Salta that has initiated the present judicial action, which the Public Defender supported.

In this manner, with that established by the laws that regulate the body's performance and that recently mentioned, it is sufficient to reject its procedural standing in the present case, rendering it inofficious to consider the grievances presented in its petition.

-VI-

Given this, the special petition lodged by the State is, in my opinion, formally admissible, because at issue is the scope and interpretation of federal regulations (resolution 1/01 of the Federal Ministry of Health – amending the similar 939/00 Obligatory Medical Program) and the definitive decision of the superior court in this case is contrary to the right that the appellant establishes in them (art. 14, sec. 3, Law 48).

In the same regard, given that the grievance based on the allegation of arbitrariness maintains a close connection to the federal question, it is appropriate to analyze both subjects simultaneously (Judgments: 325:50 and 609).

-VII-

With respect to the grievance pertaining to the viability of the chosen means in the lower court, it is appropriate to mention that the *amparo* is the simplest and briefest judicial procedure for truly ensuring the rights protected by the Fundamental Law. In this sense, the Court has repeatedly said that its objective is effective protection of rights (Judgments: 321:2823) and has made explicitly clear the essential need to use that exceptional means to safeguard the fundamental right of life and health (Judgments: 325:292 and its citations).

In effect, in the last of those precedents the Court has declared that "… the right to life is the first natural right of the human being, pre-existing all positive legislation that is guaranteed by the National Constitution (Judgments: 302:1284; 310:112 and 323:1339)".

Similarly, the Court has understood that individual life and its protection – in particular the right to health – constitutes a fundamental good in itself, that, in turn, is essential for the exercise of personal autonomy. The right to life, more than an unenumerated right in the

terms of art. 33 of the Fundamental Law, is an implicit right, as the exercise of the expressly recognized rights necessarily requires it and, in turn the right to health – especially when dealing with serious illnesses – is intimately related with the first and with the principle of personal autonomy, since a gravely ill individual is not in a condition to freely choose his own life plan. Furthermore, the court held that the right to health, from the regulatory point of view, is recognized in the international treaties of constitutional rank (art. 75, sec. 22), among them art. 12, sec. c of the International Covenant of Economic, Social and Cultural Rights; sec. 1, arts. 4 and 5 of the Convention on Human Rights – Pact of San José, Costa Rica; and sec. 1 of art. 6 of the International Covenant on Civil and Political Rights, extending not only to individual health but also to collective health (Court Reports: 323:1339). There is no doubt, therefore, that in the lower court, the *amparo* method is valid.

-VIII-

Finally, it does not help the appellant to argue that the decision is dogmatic, inflexible, and lacks scientific rigor. To the contrary, the extensive considerations that the judges formulated in both instances with respect to the entity and evaluation of the existing evidence in the case – as much that provided by the plaintiff as that from the State when presenting the Law 16.986 art. 8 report – which they concluded was sufficient to resolve the controversy, is enough to sustain the decision that they eventually adopted and that, personally, I share. In my view, the modification introduced to the original Obligatory Medical Plan in regards to the coverage of medicine in multiple sclerosis cases, its classes and variants, violated the right to health of those who suffer from this disabling disease – a guarantee safeguarded not only by national laws but also by international protection that tend to have a progressive attitude of support in the treatment of these neurological manifestations. This lack of support comes from the challenged resolution itself, that in an attempt to not violate rights in practice, decrees that “Without prejudice to the established laws in this Resolution on the coverage of medications, the same will not be able to introduce limitations to ongoing treatments at the moment it becomes effective” (see copy of p. 96, emphasis in original). This same rule, moreover, not only marks an inequality of

treatment between patients of the same class (for example, a patient with isolated demyelinating syndrome that is in treatment with 100% coverage for medications, in contrast to one who has not commenced treatment who will not have that percentage) but also undermines the Ministry of Health's only argument to uphold the validity of the resolution, which is that the exclusion of the certain cases from coverage stems from a protection of health for patients by avoiding the authorization, in this way, of unnecessary treatments in light of the lack of sound diagnostics.

On this basis, if the goal of eliminating the 100% coverage is to avoid medicine for those with the isolated demyelinating syndrome or those that have multiple sclerosis but have not had two outbreaks or exacerbations in the last two years, in order to protect their health, it does not make sense that it can be applied to the same cases if they have already commenced treatment. Either it "protects health" in all events in equal conditions, in which case the Ministry should limit all those treatments instead of ensuring coverage, even those that are ongoing, or the argument is clearly false. I am inclined to agree with the latter.

On the other hand, the test of both parties is supported by the same medical reports and from its interpretation does not arise – as the intervening courts held – any basis to determine the temporal limitation of two years for the unequivocal confirmation of the disease, as the National Ministerial Department adduced. As for that which is true, as the appellant argues, the special "Consensus on the use of immunomodulatory drugs in the treatment of multiple sclerosis in Argentina" (pgs. 51-52) expresses that patients with high-risk IDS "may" be equally treated with the medication, which implies that it is not required, and also that the medical report of pages 59-61 shows the benefit of treatment to prevent the disease from worsening. In effect, it states there that "The recognition of IDS (Isolated Demyelinating Syndrome) has had without doubt an important impact on the management of patients with MS (multiple sclerosis), and those patients probably represent a new category of future classifications of clinical forms of the disease. A unanimous consensus exists regarding the early initiation of the treatment in those patients with a specific diagnosis of MS. In patients with IDS, a careful evaluation should be made, and clear high risk factors established to appropriately select those patients that will be included in

immunomodulatory treatment plans aimed at diminishing the risk of developing clinically defined MS. This call to attention is based on: 1) IDS can present etiologies different from MS; 2) It is possible that some of those patients may present a multifocal but single-phased picture of the disease, as that which occurs in acute disseminated encephalomyelitis; 3) Patients with IDS and without clear risk factors probably do not develop new episodes consistent with the clinically defined MS diagnosis, and therefore should not be exposed to immunomodulatory treatments. In conclusion, it is clear that for the treatment of patients with IDS and at high risk of developing clinically defined MS, utilizing intramuscular IFN-betala is beneficial. Nonetheless, particular care must be given to their adequate selection, in order to include the appropriate patients in these therapeutic plans. Finally, the treatment of this group of patients must be made following guidelines similar to those recommended for the use of immunomodulatory drugs for the treatment of clinically defined Multiple Sclerosis."

In my view the imperative of the lower court is to differentiate the diagnosis of the ailment and the prescription of the drugs that fight or reduce it, from their coverage by the social welfare agencies or prepaid companies. The first is the task of the medical professionals specialized in this disease, and it is unthinkable that they would prescribe a medication that is inadvisable for its treatment, particularly with drugs that, while they are beneficial for the illness, can have important adverse effects that call for a periodic monitoring system – p. 329 – and the second is within the competence of the regulatory authority to formulate the obligatory medical plan that must necessarily be based on the best corresponding material. In any event, this debate is not, as the Ministry of Health says, safeguarding the ill from possible adverse reactions and pharmacological contraindications which I insist must be evaluated by the doctor and not by an administrative authority – but rather the degree of coverage of the remedy by the social welfare agencies and prepaid medicine companies for a type of disease considered high risk and low incidence – according to the proceedings, some 6,500 patients in the entire country – without the ministry having proven what the motive is for determining that a disabling disease that had 100% medication coverage now in some cases has none, a circumstance that, by directly affecting the right of the multiple

sclerosis patients to the protection of health, renders the act, under my criteria, arbitrary.

-IX-

Given the above-expressed, in my opinion the special petition submitted by the State (Ministry of Health) is formally admissible, the petitions by the multiple sclerosis associations of La Pampa, Mendoza, Corrientes and Argentina were incorrectly admitted, the judgment as it regards the legal standing of the Federal Public Defender is revoked in conformance with that provided in section V of this opinion, and the remainder is upheld.

Buenos Aires, 4 August 2003

SIGNED: NICOLAS EDUARDO BECERRA

Buenos Aires, 18 December 2003

Regarding the proceeding:

"Multiple Sclerosis Association of Salta v. Ministry of Health – National State on *amparo* action - injunctive relief"

Considering:

That this Court shares in the report of Mr. Attorney General of the Nation to whose premises and conclusions we refer for the sake of brevity.

Therefore, the special petition submitted by the State is declared formally admissible, the special petitions initiated by the Multiple Sclerosis Association of La Pampa, Mendoza, and Corrientes and the Multiple Association of Argentina are declared incorrectly admitted, the appealed resolution as it regards granting standing to the Public Defender is revoked and its principal parts confirmed. With costs. Notify the parties, add the complaint to the main file and, as appropriate, return it.

SIGNED: CARLOS S. FAYT (dissenting) - AUGUSTO CESAR BELLUSCIO - ENRIQUE SANTIAGO PETRACCHI - ANTONIO BOGGIANO - ADOLFO ROBERTO VAZQUEZ - E. RAUL ZAFFARONI (partially dissenting)

PARTIAL DISSENT OF MR. MINISTER DOCTOR DON E. RAUL ZAFFARONI

Considering:

That I agree with the vote of the majority so far as – with reference to the report of Attorney General – it declares the special petition submitted by the State formally admissible and confirms the principal part of the appealed judgment, with costs, and also with respect to the federal remedies that it disallows, with the exception of its holding respecting the legal standing of the Public Defender, an issue that – in my view – given the form in which the Tribunal judges declared the remaining aspects of the question, lacks relevance to the merits.

SIGNED: E. RAUL ZAFFARONI

DISSENT OF MR. PRESIDENT DOCTOR DON CARLOS S. FAYT

Considering:

That the special petition submitted by the State lacks sufficient basis. That, for its part, the petitions lodged by the Multiple Sclerosis Associations of La Pampa, Mendoza, Corrientes, The Multiple Sclerosis Association of Argentina and the Public Defender are inadmissible (art. 280 of the Federal Code of Civil and Commercial Procedure).

Therefore, and noting the Attorney General's report, the special petitions are declared incorrectly accepted and the appeal inadmissible. Notify the parties. File the complaint and return the principal proceedings.

SIGNED: CARLOS S. FAYT