REPUBLIC OF ITALY
IN THE NAME OF THE ITALIAN PEOPLE
COURT OF MILAN

Labor Division

Justice Nicola Di Leo, as labor judge, has issued the following

JUDGMENT

in the first instance civil case, registered as N. 14276/2013 RG brought forward by:

----------, with the advocacy of the Lawyer ----------
------- and GENOVESI ALESSANDRA, via Turati, 6 20121 Milan; with
with election of address for service in ----------

PLAINTIFF

----------, with the advocacy of the Lawyer----------
------- and GENOVESI ALESSANDRA, via Turati, 6 20121 Milan; with
with election of address for service in ----------

PLAINTIFF

---------- (CF.), with the advocacy of the Lawyer ----------
------- and GENOVESI ALESSANDRA, via Turati, 6 20121 Milan; with
with election of address for service in ----------

PLAINTIFF

AGAINST

MINISTRY OF HEALTH (C.F.), represented by the attorney general, e with election of address for service in VIA FREGUGLIA, l 20122 Milan, at the attorney general's law firm

DEFENDANT

SUBJECT: Compensation, Law no. 210/1992

DEVELOPMENT OF THE PROCEEDINGS

With complaint addressed to the Court of Milan, as Labor Judge, filed on 10/09/13, ----------, as parents of ---------- have summoned the MINISTRY OF HEALTH arguing that their son had contracted an autism syndrome following the vaccines described in the complaint, which would have contained, in dangerously way, some heavy and polluting metals such as aluminum - whose toxicity would increase in presence of other components such as polysorbate 80 - and mercury.

In particular, subsequently and in the immediate vicinity of the injection of three doses of the vaccine of hexavalent *lnfanrix Hexa SK* in 2006,---------- would manifest pathological

symptoms until the diagnosis of autism put in place in 10/12/10, and the causal connection with the aforementioned administration has been established only in that date.

Then, the plaintiffs attached evidence that in 4/05/2011 they had filed ritual instance for compensation to the Ministry.

However, as their instance has not been granted, the plaintiffs introduced the present proceeding, requesting to establish the right of ---------- to compensation under Law no. 210/92 for the irreversible damage suffered (in all the components set forth in Article 2, paragraphs one and two of that Law, including the special supplementary compensation and the *una tantum* (one-off) set forth in the second paragraph), with effect from the administrative claim to the Ministry, and in addition, the legal interests on arrears accrued as required by law and with the attribution of the benefit for the following period. With award of costs.

Duly appearing before the court, with an articulated defense brief, the MINISTRY OF HEALTH has challenged the validity of the claim, asking for its dismissal. With award of costs.

The defendant has exclusively observed that there should not exist any casual connection between the vaccines and the disease contracted by the child.

At the hearing for the discussion, an expert has been appointed by the court.

Then the case has been orally discussed and decided as publicly read.

THE GROUNDS FOR THE DECISION

Preliminarily, the capacity of the MINISTRY OF HEALTH to be sued has to be stated.

Indeed, the Court of Cassation has clarified that

"In matter of disputes concerning the compensation provided by the Law no. 210, February 25, 1992 in favor of persons who suffered irreversible damages due to mandatory vaccines, transfusions and the administration of blood products, and submitted in order to ascertain their right to obtain the benefit, there is the capacity to be sued of the Ministry of Health as public entity that, similarly, in administrative proceedings decides on the claim of the parties seeking for the social assistance benefit." (See Court of Cassation, Order n. 29311 of 12/28/2011).

As to the merits above all it has to be pointed out that, from the file of the case, *only the etiological consequentiality* between the syndrome of autism from which is suffering ---------- and the vaccines described in the complain appears to be *challenged by the parties*.

For this reason, in order to verify the casual connection, a technical appraisal by a court-appointed expert has been provided.

The expert confirmed that the child is suffering from syndrome of autism and he determined the casual connection between the administration of the *vaccine of hexavalent Infanrix Hexa SK* in 2006 to the child and the disease with seriousness and care, and it is possible to refer to the whole expert statement.

In particular, in any case, it can be highlighted that the court appointed expert did not limit his analysis to the *chronological criteria*, i.e. of the close time sequence between the presentation of the

disease and the injection of the vaccine, but he also analyzed, the different parties' arguments in a considered and careful way. (pages 10 and 11 of the technical appraisal by the court-appointed expert).

On this point, he has first argued that there were no reason to consider reliable the arguments of the Ministry, according to which should be backed up the autism suffered by ----------as a *genetic*

disease, as he does not consider *"any specific constant alteration of chromosomal material to be transmissible"* (page 11).

Rather, the court's expert came to consider reasonable the argument according to which, the vaccine *Infanrix Hexa SK* would contain some doses of mercury, used as disinfectant, considering reliable the data thanks to the estimation provided in the *GlaxoSmithKline*'s report, therefore justifying, the real possibilities to consider the casual incidence of the mentioned vaccine on the disease suffered by the child *more likely than not*,.

The expert, on the basis of the careful analysis set out came to the conclusion that

"it is probable, in extent certainly higher than the contrary, that the autistic disorder of the young---------- was jointly caused, on the basis of a polymorphism that has made it susceptible to the toxicity of one or more ingredients (or pollutants), by the vaccine *Infanrix Hexa SK* administrated in three doses from March to October 2006. The product, as recently resulting from confidential document of the Pharmaceutical Company which held the patent, shows a specific adversely affecting suitability for the autistic disorder, the extent of which is, theoretically small if calculated on the data of the clinical trial pre-authorization – it would explain only 2-5% of the cases of disease- actually underestimated for the presence, recently confirmed by the Australian health authority, of batches of the vaccine containing a mercury-based disinfectant, today officially banned because of the proven neurotoxicity, present in concentrations that largely exceed the maximum levels recommended for infants weighing a few pounds.

These elements, in addition of the denial at the root of the defendant's arguments, i.e. the genetic cause of the disease, the absence of mercury in the vaccine or, in any case, its harmlessness, currently validate the mentioned product as the only known cause of the disease in question, making it therefore by far the most probable of any other cause, which are so uncertain under the profile of the adversely affecting efficiency to result today relegated to the sphere of the mere hypothesis.

This consideration – and only this- allows, in the writer's opinion, to consider the etiological benchmark, known as "principle of exclusion of other causes," on which the current jurisprudence apparently based on, to be finally satisfied. This, always in the writer's opinion, has been so far misunderstood and confused with the chronological one, of the *post hoc, propter hoc,* considered – mistakenly- that the vaccines, until few months ago officially unrelated to the pathogenesis of autism, could be elevated to the dignity of probable cause for the mere lack of valid alternative. Actually, until GlaxoSmithKline (producer of the mentioned product, remark of the author) did not acknowledge, albeit unintentionally, the five cases of autism that have emerged during the clinical trial of *Infanrix Hexa SK*, the casual connection between vaccines and disease was, like any other etiopathogenetic hypothesis, a mere possibility. This, evidently, made the succession of the two facts (administration of vaccine and the progressive autistic regression) far more easily accidental than not."

Based on the technical report carried out in this proceeding, therefore, *it is more probable, in an extent certainly higher than the contrary*, that the autism disorder of ---------- has been *caused*, or at

least *jointly caused,* on the basis of a polymorphism that made it susceptible to the toxicity of one or more ingredients (or pollutants) from the vaccine *lnfanrix Hexa SK* administered in three doses from March to October 2006.

Regarding the etiological nexus, the Court of Cassation has clarified that

" in terms of civil liability, in case the harmful event is linked to more actions or omissions, the problem of the contributory causes finds a solution in article 41 of the Criminal Code – a rule of general nature, applicable in civil lawsuits concerning liability – under which the concurrence of preexisting, simultaneous or arisen causes, even if independent from the omission of the guilty party, does not exclude the causal relationship between the mentioned causes and the event, being this latter attributable to all of them" (See Court of Cassation, Order n. 15537 of 07/14/2011).

It is possible, after all, to observe how the analysis of the court appointed expert can be, at this point, even further confirmed by the close temporal sequence between the identified pathological disorders and the administration of the vaccine, which has not been challenged by the sued Ministry.

Having been the casual connection between the vaccine and the disease established, regarding the classification of the disease, it is not contested by the parties that this latter [the disease] *is attributable to the first category of the attached Table A* of the Presidential Decree no. 834 of 1981 (see attachment at page 40 of the complaint, not challenged in the defense brief, in which only the existence of the etiological relationship has been challenged, and, in any case the document 2, attachment 26 of the complaint.).

This classification being acknowledged, at this point, the plaintiffs request to obtain from the Ministry the payment of all the amounts mentioned in article 2, paragraph one and two, of the Law no. 210 of 1992, according to the amount specified in the decision and also the arrears accrued from 5.01.2011 (first day of the month following the date of the administrative instance of the 4.05.2011: see document 4 of the complaint) must be, therefore, upheld.

In particular, the Ministry has to be condemned to pay the compensation referred to in article 2, paragraph 1, of the above mentioned Law, to the extent required, as well as the special supplementary compensation to the plaintiffs.

Moreover, the plaintiffs' right to the revaluation of both the compensation and the special supplementary compensation, according to programmed annual rate of inflation, as referred to in article 2 of the Law no. 210 of 1992 has to be declared, having the Court of Cassation clarified that

"In the subject matter of damages arising out of transfusions and administration of blood products, the special supplementary compensation provided by article 2, paragraph 2, of Law no. 210 of 1992 is subject to an annual reassessment, after the decision no. 293 of 2011 of the Court of Cassation, that has declared the exclusion of the revaluation to be illegitimate because it violates of the principle of equality in relation to the regulation, set forth by the article 2, paragraph 363, of the Law no.244 of 2007, of the damages from administration of thalidomide. Since, however, the reference to that legislation has been identified by the Constitutional Court as mere "*tertium comparationis*" of the judgment of legitimacy, the attribution of the revaluation is not anchored to the entry into force of the Law no. 244 of 2007" (See Court of Cassation, Order no.10769 of 06/27/2012; decision no. 22256 of 09/27/2013)

Moreover, the interests accruing from the 121th day of the application of 04/05/2011 have to be considered, having to contemplate that, also for that type of welfare credit, what the Constitutional Court has held in the decision no.156/91, according to which also the time for the definition of the administrative proceedings has to be taken in account, is valid.

Finally, considering that the plaintiffs have demonstrated how the hexavalent vaccine *lnfanrix Hexa SK* falls within the mandatory vaccines under the Law (see the document from the ASL of the 1/12/06 that lists the "mandatory vaccines", including, for the pathologies to be prevented – as mentioned - the vaccine in question: see attachment 8 at the document 2 of the complaint), it is possible to recognize to the plaintiffs, pursuant to article 2, paragraph 2, Law no. 210/92 – for the period between the harmful event in date 10.12.10 (see the hearing report and the document 2, attachment 30 and document 4 attachment 6 of the complaint) and the obtaining of the compensation, i.e. until the date of this decision- a one-off allowance in equal amount, for each year, of the 30% of the compensation owed to under the paragraph 1 of article 2 of the same Law, with exception for that heading, the legal interest and the currency revaluation.

Indeed, article 1, paragraph 1 and article 2, paragraph 2, of the Law 210 of 1992, foresees that

Article 1, paragraph 1: "who, *because of mandatory vaccine* required by law or by order issued by an Italian heath authority, has contracted injury or infirmity, from which a permanent impairment of psycho-physical integrity has derived, has the right to compensation from the State, according to the condition and manners required by this law";

Article 2, paragraph 2: "(…) to the persons referred to in the paragraph 1, of the article 1, even if the compensation has already been granted, is paid, upon application, for the period between the occurrence of the harmful event and the grant of the compensation provided by this law, a one-off allowance in equal amount, for each year, of the 30% of the compensation owed pursuant to paragraph 1 and the first period of this paragraph, with exception for the legal interest and the currency revaluation.

Therefore, following the conjunction of these two articles, since the hexavalent lnfanrix Hexa SK is a *"mandatory vaccine"* that certainly falls in the aforementioned article 1, paragraph 1, the one-off allowance provided by the aforementioned article 2, paragraph 2 (see Court of Cassation, decision no. 8976 of the 04/07/2008) has to be acknowledged to the plaintiffs.

The condemnation of the Ministry is pronounced in this sense in the ruling.

Finally, because of the negative outcome, the court-appointed expert costs it must be charged jointly to the parties and, in the internal relationship between them those costs have to be borne by the defendant, with right of reimbursement for the plaintiffs of what they might have already paid to the court appointed expert, with cash settlement made as required by the separate order.

Likewise, the litigation costs are paid, according to the principle of the negative outcome, as established in the ruling, according to the value and the duration of the proceeding.

FOR THESE REASONS

1. the right of ---------- to the compensation as provided for in article 2, paragraph 1, Law n.210/92 being established, the court condemns the MINISTRY OF HEATH to pay the compensation in the amount required in Table A of the Presidential Decree no. 834/81 for the category I, united with the sum corresponding to the amount of the special supplementary compensation provided for in Law no .324, May 27, 1959, with condemnation to the payments the related deposits and with effect from the first day of the month following the application of the 04/05/2011, plus the accessory amounts required by law from the 121th day following the application to the plaintiffs.
2. The court condemns, therefore, the defendant Ministry to pay the compensation in the required amount to the plaintiffs, declaring the plaintiffs right to the revaluation of both the compensation and the special supplementary compensation according to programmed annual rate of inflation, as referred to in article 2 of the Law no. 210 1992.
3. Pursuant to Article 2, paragraph 2, of the Law no. 210/92 for the period between the harmful event in date 10.12.10 and the obtaining of the compensation, i.e. until the date of this decision, the Court condemns he Ministry to pay a one-off allowance in equal amount, for each year, of the 30% of the compensation owed to under the paragraph 1 of the Article 2 of the same law, with exception for that heading, the legal interest and the currency revaluation to the plaintiffs.
4. The court condemns the Administration to the related payments, charges the court-appointed expert costs jointly to the parties and, in the internal relationship between them those costs have to be borne, by the defendant, with the right of the plaintiffs of the reimbursement of what they might have already paid to the court appointed expert, with cash settlement made as required by the separate order issued in the same date. The court condemn the defendant to reimburse the court fees, in settlement a total of Euro 3000 in addition to IVA and CPA to the plaintiffs.

The court fixes the term of 60 days for the filing of the judgment.
The decision is temporary executive.

Milan, 09/23/2014

The Judge
Dr. Nicola Di Leo