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The *European Review of Private Law* aims to stress the strong practical as well as academic importance of national private laws in intergrating Europe, in the face of the current overwhelming emphasis placed on European Community Law. Cross border research will become increasingly important as cross border legal work develops. There is a need for a law review which focuses on legal developments within a broad European perspective, and which provides a platform for debate on the desirability of a unified private law in Europe, as a complement to economic, monetary and political union.

The European Review of Private Law will have an appeal across the academic/practitioner divide. By providing accessible and comparative surveys of legal developments in a number of countries, with summaries of articles and case notes in French, German and English, the Review will provide a valuable source of information for lawyers wishing to look for new ideas with which to tempt their courts to innovate in private law. The impact of European Community law has made national courts more receptive to importing new conceptual devices and legal techniques directly from foreign case law, not always waiting for the legislature to act.

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The Italian Ministry of Health Held Liable for the Damages Arising out of Contaminated Blood and Blood Products

Nadia Coggiola Università di Torino

1. The Decision of the Italian Corte di Cassazione

With its decision dated 31 May 2005 n° 11609[1] the Italian *Corte di Cassazione* definitively held the Italian Ministry of Health liable in tort for the damages suffered by the numerous petitioners who had contracted HIV, HBV and HCV infections as a consequence of infected blood transfusions or in takings of infected blood components.

The case arose a large interest in the public opinion, due to the large number of plaintiffs (more then 200 people brought suit against the Ministry in the first instance court, even if their number decreased following many private settlements), the severity of the illnesses suffered and the fact that the Ministry of Health was the defendant.

The main issues of the case were if the Ministry of Health could be held liable in tort for the damages and which rules it had violated. Furthermore, the Court was asked to state on the relationship between the liability in tort of the Ministry and the rules of Legge 210 of 25 February 1992,[2] which provides an indemnity for damages consequent to compulsory vaccinations, transfusions and blood products in takings.

The Corte di Cassazione held the Ministry of Health liable for the damages consequent to infected blood products transfusions and in takings, because it had violated the provisions of article 2043 of the Italian Civil Code[3], the general tort rule of the Italian liability system. So it upheld the decisions of the two previous instances, the Tribunale di Roma[4] and the Corte di Appello di Roma.[5]

The Court stated that the Ministry of Health was liable because it had negligently omitted to pursue its duties of monitoring and vigilance on the production and

* The author wishes to thanks Professor Michele Graziadei, Professor of Comparative Private Law at the Università del Piemonte Orientale, for his support and advice and Professor Simon Whittaker, Professor of European Comparative Law at Oxford University for reading the first version of this note and for his helpful remarks

1 Cass. (*Corte di Cassazione*), sez. III, 31 May 2005 n° 11609, in *Resp. civ. (Responsabilità civile e previdenza),* 2006, 101, note at page 294 by N. COGGIOLA, 'La Cassazione afferma la responsabilità del Ministero della Salute per i danni da sangue ed emoderivati infetti'.

2 published in the G.U. (Gazzetta Ufficiale) 6 March 1992, n. 55.

3 Cass., sez. III, 31 May 2005 n° 11609, at 11.1.

4 Trib. (Tribunale) Roma, 27 November 1998, in *Foro it (Foro Italiano).,* 1999, I, 313, with note by U. IZZO, 'Circa la responsabilità per danni da trasfusioni di plasma ed emoderivati infetti da HIV'*; Giust. civ. (Giustizia Civile),* 1999, I, 2851, with note by P. COSTANZO, 'La responsabilità della Pubblica Amministrazione per omissione di controlli: danni da trasfusione di emoderivati infetti'.

5 App. (Corte di Appello di) Roma, 23 October 2000, in *Danno e resp. (Danno e responsabilitá),* 2001, 1067, with note by IZZO, 'La responsabilità dello Stato per il contagio di emofilici e politrasfusi: oltre i limiti della responsabilità civile', *Dir. uomo (I diatti dell' uomo)*, 2000, fasc. 3.

marketing of the blood products. Therefore, the conduct of the defendant violated the principle of *neminem laedere,* stated in article 2043 of the Italian Civil Code, which represents the leading principle of action for any person, included public authorities

Furthermore, the same Court affirmed that the action for the compensation in tort and the application for the indemnity provided for by Legge 210/92 have a different nature and require different assumptions. Consequently one action doesn't bar the other one.

2. The Previous Italian Case Law on Defective Blood Products Liability

Under the Italian system of civil liability, product damages that amount to the death or the personal injury of a person can be claimed both in a penal lawsuit and in a civil action.

In turn, the civil action claim can affirm that the defendant violated the D.P.R. 224 of 24 May 1988, implementing the CEE Directive 85/374 of 25 July 1985 on defective products or the Civil Code rules on tort liability, such as the general rule on extra contractual liability provided for by article 2043[6] and the rule on the liability of the persons involved in harmful activities contained in article 2050.[7]

It must be stressed that even if D.P.R. 224/1988 is generally more favourable to the damaged subject, that only needs to demonstrate the damage, the product defect and the causation, shifting on the producer the burden to demonstrate he was not negligent, sometimes an action in compensation under article 2043 Civil Code can be equally profitable. In fact, the more onerous task of probation required by article 2043 Civil Code, the demonstration by the damaged person of the producer negligence, often becomes a mere 'virtual task',[8] as the Italian courts frequently presume the existence of that same negligence.[9]

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[6] Article 2043 Italian Civil Code *'Any fraudulent, malicious or negligent act that causes an unjustified injury to another, obliges the person who has committed the act, to pay damages'.* Translation by M. BELTRAMO, G.E. LONGO and J.H. MERRYMAN, *The Italian Civil Code,* Oceana Publications Inc., Dobbs Ferry, N.Y., 1991.

[7] Article 2050 Civil Code '*Whoever causes injury to another in the performance of an activity dangerous by its nature or by reason of the instrumentalities employed, is liable for damages, unless he proves that he has taken all suitable measures to avoid the injury'.* Translation by M. BELTRAMO, G.E. LONGO and J.H. MERRYMAN, *The Italian Civil Code,* op. cit. ftn. (6).

[8] A. PALMIERI, 'Dalla 'mountain-bike alla bottiglia d'acqua minerale: un nuovo capitolo per un'opera incompiuta', *Foro it.,* 1998, I, 3664 e R. PARDOLESI, 'La responsabilità per danno dei prodotti difettosi' R. PARDOLESI e G. PONZANELLI (eds.), *Nuove leggi civili commentate.,* 1989, pp 649-651, p 650.

[9] U. CARNEVALI, 'Responsabilità del produttore e prova per presunzioni', *Resp. civ.,* 1996, 481; e.g. see: Cass., 25 May 1964, n. 1270, *Foro it.,* 1965, I, 2098, annoted by F. MARTORANO, 'Sulla responsabilità del fabbricante per la messa in commercio di prodotti dannosi (a proposito di una sentenza della Cassazione)', *Foro it*., 1966, V, 13; Trib. Napoli, 5 December 1969, *Giur. merito (Giurisprudenza di Merito),* 1971, I, 297, with note by G. ALPA, 'Prodotti difettosi, danno ingiusto, responsabilità del fabbricante', Cass., 10 November 1970, n. 2337, *Giur.it. (Giurisprudenza Italiana)*, 1973, I, 1, 1205, with note by G. ALPA, 'Errori di progettazione e responsabilità del costruttore'.

As a matter of fact, Italian courts, both before the implementation of the CEE Directive 85/374 on defective products[10] and after it,[11] have constantly affirmed that the production of pharmaceutical and blood products is a dangerous activity and consequently stated the liability of the producer of those products on the basis of article 2050 Civil Code.

Under article 2050 Civil Code the plaintiff only have to demonstrate the causation between the performance of the dangerous activity and the resulting injury, but not the defect of the product, while the producer must prove he has taken all suitable measures to avoid the injury.

The decision of the European Court of Justice of 25th April 2002, on the cases C-52/00, C-154/00 e 183/00,[12] will probably influence that

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[10] Cass., 15 July 1987, n. 6241, *Foro it.,* 1988, I, 144, with annotation by D. CARUSO, 'Quando il rimedio è peggiore del male: emoderivati infetti e responsabilità civile'*; Resp. civ.,* 1988, 406, with annotation by G. TASSONI, 'Responsabilità del produttore di farmaci per 'rischio da sviluppo' e art. 2050 c.c.'; Trib. Milano, 19 November 1987, *Foro it.,* 1988, I, 144, with annotation by D. CARUSO, op. cit. ftn. (10); *Resp. civ.,* 1988, 407, with annotation by G. TASSONI, op. cit. ftn. (10); App. (Corte di Appello) Trieste, 16 June 1987, *Resp. civ.,* 1989, 334. *Contra* Trib. Napoli, 9 October 1988, *Resp. civ.,* 1988, 407, with annotation by G. TASSONI, op. cit. ftn. (10), in which the liability of the pharmaceutical product producer was based on Article 2043 Civil Code, and it was excluded the same production could be deemed to be a dangerous activity and Article 2050 Civil Code applied to the case. On the three decisions jointly even see the comment of U. CARNEVALI, 'Nuove frontiere della responsabilità del produttore: farmaci difettosi e prevenzione del rischio'*, Resp. civ.,* 1989, 225.

[11] Trib. Roma, 20 June 2002*, Foro it.,* 2002, I, 3225*; Danno e resp.,* 2002, 984, with annotation by L. LA BATTAGLIA, 'Danno da prodotto farmaceutico difettoso e prova liberatoria'; *Resp. civ.*, 2002, 1103, with annotation by U. CARNEVALI, 'Farmaco difettoso e responsabilità dell'importatore-distributore'; Trib. Ravenna, 28 October 1999, *Danno e resp.,* 2000, 1012; Cass., sez. III, 27 January 1997, n. 814, *Foro it. Rep.,* 1997, entry *Responsabilità civile* [5760], n. 211; Cass., sez. III, 1 February 1995, n. 1138, *Discipl. comm. (Disciplina del Commercio e dei Servizi),* 1995, 592; Cass. Sez. III, 20 July 1993, n. 8069, *Foro it.,* 1994, I, 455, *Resp. Civ.,* 1994, 61, with annotation by A. BUSATO, 'I danni da emoderivati: le diverse forme di tutela'*, Giust. Civ.,* 1994, I, 1037, with annotation by A. BARENGHI, 'Brevi note in tema di responsabilità per danni da emoderivati difettosi tra obiter dicta e regole giurisprudenziali'; Cass., sez. III, 27 July 1991, n. 8395, *Giur. It.,* 1992, I, 1, 1332, with annotation by A. BARENGHI, 'In tema di farmaci difettosi', *Nuova giur. civ., (Nuova giurisprudenza civile commentata)* 1992, I, 569; App. Roma, 17 October 1990, *Giur. it,* 1991, I, 2, 816, with annotation by G. TASSONI, La produzione di farmaci tra l' art. 2050 c.c. ed i cosiddetti 'development risks'.

[12] EC Court, 25 April 2002, cases 52/00, 154/00 e 183/00, ECR *(European Community Reports)* I, 3827, with annotations by *T. ZANKEL,* 'Umsetzungsspielraum bei der Produkthaftungsrichtlinie', *E.L.R. (European Law Reporter),* 2002, 190-191, G. RAYMOND, *Contrats – concurrence – consommation,* 2002 n° 7 26-28, F. ENDRÖS.*,* 'Fehlerhafte Umseztung der Product-haftungsrichtlinie in Frankreich', *PHI (Produkthaftpflicht international),* 2002 154-155, J. CALAIS-AULOY*,* 'Menace européenne sur la jurisprudence française concernant l'obligation de securité du vendeur professionnel*' D. (Recueil Dalloz),* 2002 Chr. 2458-2461, M. SCHLEY, 'Französisches Produkthaftungsrecht fehlerhafte Umsetzung der Produkthaftungsrichtlinie 85/374/EWG'*, Recht der internationalen Wirtschaft,* 2002, 785-787; G. VINEY, 'L'interpretation par la CJCE de la Directive du 25 Juillet 1985 sur la responsabilité du fait des produites défectueux'*, JCP édition générale (La Semaine juridique)* 2002, 177; G. LETT, 'Produktansvar for mellemhandlere', *Ugeskrift for Retsvæsen,* B, 2002, 398-399; R. KLAGES*, Revue du droit de l'Union européenne,* 2002, n° 2, 379-382; A. VALTOUDIS*, Elliniki Epitheorisi Evropaïkou Dikaiou,* 2002, 817-861; V. ULFBECK, 'Totalharmonisering af

case law.[13]

In that occasion, the EC Court in fact substantially held that the goal of the CEE Directive 85/374 is rather the harmonisation of the national tort systems then the protection of the subject injured by the defective product. As a consequent, the national juridical systems cannot guarantee the consumers a protection broader then those provided for by the European Directive.

3. The Reasoning of the Corte di Cassazione

Contrary to the first instance court, which held the Ministry of Health was liable for the damages consequent to the defective blood products transfusions and in takings on the basis of articles 2043, 2049 and 2050 of the Civil Code,[14] both the second instance court[15] and the Corte di Cassazione[16] affirmed the same Ministry was liable only because it violated the single article 2043 Civil Code.

The Corte di Cassazione excluded the application of article 2049 Civil Code, which provides the liability of masters and employers for the damages caused by unlawful acts of servants and employees in the exercise of the functions to which they are assigned, because it affirmed the public authorities charged of the duty to administer the blood products were independent legal persons, distinct from the Ministry of Health.

The same Court also excluded the application of article 2050 Civil Code to the case, asserting that the Ministry of Health was not the producer of the defective blood products and consequently didn't perform any dangerous activity.[17]

It's evident that the petitioner didn't claim their damages against the Ministry of Health on the basis of D.P.R. 224/1988 for the reason it was not the producer of the defective blood products.

So, the Italian Ministry of Health was held liable exclusively on the basis of article 2043 Civil Code alone, in force of its negligent omissions to its duties of direction and vigilance, that is to say of its violation of the principle of *neminem*

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produktansvaret - Køberetlige regler som alternativ til mellemhandlerhæftelsen?', *Ugeskrift for Retsvæsen* B 2003 1-6; N. JONQUET, A.-C. MAILLOLS; F. VIALLA, 'Les victimes de produits de santé épargnées par la CJCE', *D.,* 2003, 1299-1301; A. GORNY, *LPA (Les Petites affiches),* 2003, n° 93, 4-6; R. SCHAUB, 'Abschied vom nationalen Produkthaftungsrecht? Anspruch und Wirklichkeit der EG-Produkthaftung – Zugleich Besprechung der Urteile des EuGH vom 25. 4. 2002, Rs. C-52/00, C-154/00 und C-183/00', *Zeitschrift für europäisches Privatrecht,* 2003, 562-589; PINNA A., *Tilburg Foreign Law Review,* 2003, 485-490; S. ROBIN-OLIVIER, J.-S. BERGÉ, 'Le rôle conféré par le droit communautaire aux droits nationaux', *LPA,* 2003, n° 99, 9-12, A. PALMIERI, R. PARDOLESI, 'Difetti del prodotto e diritto privato europeo', *Foro it.,* 2002, IV, 294-303; G. PONZANELLI, 'Armonizzazione del diritto v. protezione del consumatore: il caso della responsabilità del produttore', *Danno e resp.,* 2002, 728-730

[13] PALMIERI and PARDOLESI, 'Difetti del prodotto e diritto privato europeo', op. cit. ftn. (12), p. 300.

[14] Trib. Roma, 27 November 1998, cit. ftn. (4), at 3.

[15] App. Roma, 23 October 2000, cit. ftn. (5).

[16] Cass., 31 May 2005 n° 11609, at 11.1.

[17] App. Roma, 23 October 2000, cit. ftn. (5).

laedere that must guide the actions of the public authorities, both in mandatory and discretional activities.[18]

The Court applied the traditional Italian case law on causation to affirm the existence of a causation link between the Ministry of Health omissions and the damages. This case law states the existence of a causation link between an action and a final event only if the latter wouldn't occur in the absence of the first (so called *conditio sine qua non* theory), but limits the application of that rule only to the events foreseeable at the time of the action, on the basis of a statistical computation (so called *teoria della causalità adeguata* or *teoria della regolarità causale*).[19]

With reference to the period of time in which the Ministry of Health could be held liable, the Court stated that, since the liability of the agent depends upon the foreseeability of the event, and the omission of the defendant must consist in a negligent action that violates a rule of conduct, the liability of the defendant could be affirmed from the moment the scientists knew HBV, HIV and HCV virus existed and how to identify them.[20]

Article 2043 Civil Code even requires the existence of the fault of the defendant to deem it liable. On that issue, the Court affirmed that the Ministry was not at fault and so could not be held liable for the damages that are the consequence of transfusions and in takings happened when the viruses were unknown.[21]

The Court added that otherwise, to affirm the Ministry liability for the lapse of time during which the viruses were unknown would mean to hold the Ministry liable on the basis of rules extraneous to the Italian tort system. The same rules would even be stricter then that provided for by article 7 letter e) of CEE Directive 85/374 in cases of 'development risk', which requires the producer to prove that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered.

It must not be forgotten that the EC Court stated with reference to that rule that it is necessary that the scientific and technical knowledge were accessible to him when the product was put into circulation to affirm the producer liability.[22]

Consequently, the Corte di Cassazione stated that the Italian Ministry of Health could be held liable only for the period of time following the date in which

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[18] Cass., 31 May 2005 n° 11609, at 13.3.

[19] Cass., 31 May 2005 n° 11609, at 20.

[20] Cass., 31 May 2005 n° 11609, at 21.

[21] Cass., 31 May 2005 n° 11609, at 22.

[22] EC Court, 29 May 1997, C-300/95, *Commission* v. *United Kingdom and others*, in *ECR* I, 2649; annoted by G. PONZANELLI, 'Regno Unito, Corte di Giustizia ed eccezioni dello state of art'; *Foro it.,* 1997, IV, 388-392; M. NOVAK*, St. Galler Europarechtsbriefe,* 1997, 305-307; H.A.G TEMMINK, *Tijdschrift voor consumentenrecht* 1997, 315-316; M.R MOK, *TVVS ondernemingsrecht en rechtspersonen,* 1997, 257-258*.;* F. GAZIN, *Europe,* 1997 Juillet Comm. n° 228 p.16–17; R. O'DONOGHUE, *European Current Law,* 1997 Part 11 p. IX-XII; P. BONASSIES, *Le droit maritime français* 1998, 32-33; A. PENNEAUX, *D.,* 1998 Jur. p. 490–493.

the tests to individuate the viruses become operational (respectively year 1978 for HBV, 1985 for HIV and 1988 for HCV), and not from the date in which it was generally ascertained that blood transfusions or blood products in takings could give raise to infections.[23]

Regarding the issue of the assessment of the causation between the damages and the infected blood products transfusions, the Corte di Cassazione held that the first instance Courts correctly asserted it on the basis of the medical documents and records of the hospital medical boards, made for the purpose to check the health conditions of the persons applying for the indemnities provided for by Legge 210/1992.[24]

Lastly, the same Court affirmed that the action for the compensation of damages provided for in article 2043 Civil Code is compatible with the application for the indemnities disciplined in Legge 210/1992, because the first action depends on an illicit act and requires the assessment of the causation between the illicit act and the damages and of the measure of the damages, while the right to the indemnity automatically arises when an irreversible damage is the consequence of a post-transfusion infection, and its measure is fixed by the law.

As the Court was not asked to pronounce on the question, it didn't give its opinion on the issue of the chance to cumulate the two benefits or the necessity to avoid such an accrual.[25]

The task of the definitive quantification of the compensable damages was left to the first instance Court. That Court had already stated in its appealed decision that the compensation of the complained damages had to be comprehensive of every item of damages: material, moral, relational and biological.

4. Considerations on the Decision of the Court

No doubt this case can be deemed important to Italian national case law on tort liability, both because it is the first time the Ministry of Health is held liable by the Corte di Cassazione for the compensation of the damages arising out of contaminated blood and blood products, and because article 2043 Civil Code was used to affirm its liability.

Regarding the application of article 2043 Civil Code to state the Ministry liability, it must be pointed out that the application of the national rules of implementation of CEE Directive 85/374 on product liability to the case was excluded, because the Ministry was not the producer or the trader of the infected blood products. Actually, its only duties in the field of blood and blood products production and distribution were the vigilance and supervision of those activities.

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[23] Cass., 31 May 2005 n° 11609, at 23.

[24] Cass., 31 May 2005 n° 11609, at 11.2 and 13.4; *cfr.* Trib. Roma, 27 November 1998, cit. ftn. (4), at 8); App. Roma, 23 October 2000, cit. ftn. (5).

[25] Cass., 31 May 2005 n° 11609, at 13.2.

For similar reasons the Ministry could not be held liable under the provision of article 2050 Civil Code, as it didn't perform any dangerous activity.

As a consequence, the Corte di Cassazione could only state the liability of the Ministry of Health on the basis of the general rule on tort liability of the Italian system, article 2043 Civil Code, which provides that: '*Any fraudulent, malicious or negligent act that causes an unjustified injury to another, obliges the person who has committed the act, to pay damages*'.

It is important to point out that that rule, thanks to its general applicability, has often been applied by the Italian courts in cases in which there was the exigency to enlarge risk and damages categories. Besides, the application of article 2043 Civil Code has been frequently matched by the reversion of the burden of proof from the plaintiff to the defendant or the presumption of the negligence of the latter.

For example, article 2043 Civil Code had often been used in cases of product damages before the implementation of the CEE Directive 85/374, when no special tort rule protected the damaged persons against the defective products and the existing contractual liability rules were enforceable only to the party of the contract. The application of the general tort rule contained in article 2043 Civil Code permitted in fact the damaged person to directly sue the producer of the defective product, assuming a negligence of the latter.

In the leading case on product liability, the *Saiwa case*,[26] the buyer of a biscuit box and his wife were damaged by a product gone by. As the reseller liability was not proved, the Corte di Cassazione held correct the statement of the appellate judge, affirming the liability of the producer on the basis of a presumptive reasoning of the causation between the producer negligence in the production and the product alteration.

So the burden of proof was shifted from the damaged person to the producer and as this latter was not able to prove he was not negligent, he was held liable for the compensation in force of the application of article 2043 Civil Code.

This juridical device had been frequently applied to other subsequent cases, in which the negligence of the producer was equally presumed by the courts.[27]

In truth, in our case the Corte di Cassazione didn't held the Ministry of Health liable because it found out some distinctive omission or actions, but since it found out the public authority omitted to pursue its general duties of vigilance and

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[26] Cass., 25 May 1964, n. 1270, cit. ftn. (9).

[27] Trib. Napoli, 5 December 1969, *Giur. merito,* 1971, I, 297, with note by G. ALPA, 'Prodotti difettosi, danno ingiusto, responsabilità del fabbricante'; Cass., 10 November 1970, n. 2337, *Giur.it.*, 1973, I, 1, 1205, with note by G. ALPA, 'Errori di progettazione e responsabilità del costruttore'; Trib. Monza, 11 September 1995, *Resp. civ.*, 1996, 371, with note by C. MARTORANA, 'L'orditoio: una macchina che non offre le sicurezze che si possono legittimamente attendere . . . le persone di non alta statura'; Cass., sez. III, 20 April 1995, n. 4473, *Resp. civ.*, 1996, 672, with note by A. DE BERARDINIS, 'La responsabilità extracontrattuale per danno da prodotti difettosi'; Trib. Verona, 23 February 1995, *Nuova giur. civ. (Nuova Giurisprudenza Civile),* 1996, I, 305 with note by S. MOGLIA, 'Infortunio sul lavoro e pluralità di responsabili'.

coordination. Or, in the words of the Court, because of its '*negligent failure to comply with its institutional duties of vigilance, direction and authorisation of human blood and blood products production and marketing*'.[28]

It is the first time the Italian Corte di Cassazione makes use of the juridical device applied to the Saiwa case to a case concerning the compensation for damages arising out of contaminated blood and blood products.

And it's even one of the rare cases in which the Corte di Cassazione held a public authority liable for omissive violation of its supervision duties. In fact, Italian case law traditionally restrained from holding liable a public authority for negligent violation of its supervision duties,[29] and only very recently this precedent has been reversed, although in a limited number of cases.[30]

Surely policy reasons of protection and compensation of the damaged persons underlied the decision of the Corte di Cassazione on the case.

Lastly, it is important to take note of the unfortunately limited considerations that the Court made on the issue of the relationship between the torts compensation provided for by article 2043 Civil Code and the statutory compensation provided for by Legge 210/92. In fact, the Court affirmed that the two rules have different assumptions and purposes, and so both compensations could be claimed, but it didn't state, because not asked to do so, if the two pecuniary compensations are mutually exclusive or cumulative.

The last issue has been at the centre of a long and unfinished discussion in Italian jurisprudence.

The Italian Corte Costituzionale, who had been frequently asked to pronounce on Legge 210/1992,[31] stated that the indemnity provided for by the

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[28] Cass., 31 May 2005 n° 11609, at 11.1.

[29] On the tortious liability of the public authorities in Italy see: R. CARANTA, *La responsabilità extracontrattuale della pubblica amministrazione,* Giuffré, Milano, 1993, especially p. 103 ff. on the issue of the scarce or barely existent application of compensation liability rules arising out of supervision duties.

[30] Only lately the Corte di Cassazione held the Consob, that is to say the Italian public authority in charge of the control of the stock market, liable, because it omitted to comply its supervising duties: Cass., sez. I, 03 March 2001, n. 3132, *Foro it.*, 2001, I, 1139 with note by A. PALMIERI, 'Responsabilità per omessa o insufficiente vigilanza: si affievolisce l'immunità della pubblica amministrazione'; *Società*, 2001, 565, with note by P. ANELLO, 'Responsabilità della Consob per omissione di vigilanza e risarcibilità del danno'; *(Ie conniglio di stato)* Cons. Stato, 2001, II, 1829 (m), with note by P. CARNEVALE, 'Brevi considerazioni sui poteri delle Autorità vigilanti indipendenti e, in particolare, della CONSOB'. For the liability arising out of the omission to supervise public goods with hidden defects, such as a trap or a deception of the public road: Cass., sez. III, 30 July 2002, n. 11250, *Rep. Foro it.,* 2002, entry *Responsabilità civile* [5760], n. 287. For the liability arising out of the omission to supervise the construction of a building: Cass., sez. III, 29 April 1996, n. 3939., *Rep. Foro it.,* 1996, entry *Responsabilità civile* [5760], n. 145.

[31] Corte Cost., 16 October 2000, n. 423, *Foro it.,* 2001, I, 4, and Corte Cost., 27 June 2000, n. 226, *Foro it.,* 2001, I, 5, both with note by G. PONZANELLI, 'Responsabilità civile e sicurezza sociale: un decennio 'tribolato'; Corte Cost., 26 February 1998, n. 27, *Foro it.,* 1998, I, 1370, with note by

law in cases of damages arising out of blood products transfusions or in takes has a relief scope.

As a consequence of the character of that indemnity, the Courts normally held that the statutory compensation provided for by Legge 210/1992 is alternative to the action for the compensation under article 2043 civil code, especially in cases in which the defendants are National Health System authorities.[32]

But in a later decision it was held that the two actions can be cumulated, even if it must be avoided the unjust enrichment of the damaged person, making subtractions of the amounts already received from the indemnity or compensation.[33]

The differences between the two remedies are clear. The compensation provided for by article 2043 Civil Code is aimed to compensate all the damages complained by the injured person, in cases of damages that are a consequence of an illicit act made with negligence, fraud or malice. The statutory compensation provided for by Legge 210/1992 is a relief indemnity that leaves aside any problem concerning the fault of the author of the injurious act, and consisting in a fixed amount of money unrelated from the actual size of the damages, and handed by the Ministero della Salute.

But even if the theoretical distinction between the two remedies is clear, the problem of the coordination of the two remedies, when they happen to result in a double compensation of the same damages and, even more, when it happens that the liable tortious defendant is the same Ministero della Salute already obliged to pay the statutory awards, is still unsolved.

5. Comparative Hints on Contaminated Blood and Blood Products Compensation

Compensation claims concerning damages arising out of contaminated blood and blood products transfusions and in takings are probably to be found in every European Union Member State. Due to the lack of space, I'll be able to concentrate my attention only on two of those experiences, the French and the English.

Traditionally French case law always held the existence of a contractual liability between hospital and patient for all the damages occurred to the latter as the consequence of acts occurred in the hospitals.[34]

G. PONZANELLI, 'La misura dell'indennizzo per le 'vittime' di vaccinazioni obbligatorie: il nuovo intervento della Corte costituzionale', *Giur. it.,* 1998, 1479, with note by A. ALGOSTINO, 'Salute dell'individuo e salute della collettività: il diritto all'indennizzo anche nel caso di vaccinazioni antipoliomielitiche non obbligatorie'; Corte Cost., 18 April 1996, n. 118, *Foro it.,* 1996, I, 2326, with note by G. PONZANELLI, ''Pochi, ma da sempre': la disciplina dell'indennizzo per il danno da vaccinazione, trasfusione o assunzione di emoderivati al primo vaglio di costituzionalità'.

[32] Cass., sez. lav., 12 November 2003, n. 17047, *Mass. Foro it.,* 2003; Cass., sez. lav., 9 May 2003, n. 7141, *Mass. Foro it.,* 2003, *Rep. Foro it.,* 2003, Lavoro e previdenza (controversie) [3880], n. 209; Cass., sez. lav., 21 October 2000, n. 13923, *Dir. giust (Diatto e giustizia),* 2000, fasc. 39, 61, with note by ROSSETTI, 'Sulla liquidazione del danno biologico resta il rischio dei doppi risarcimenti'.

[33] Trib. Roma, 8 January 2003, *Foro it.,* 2003, I, 622; *Giur. it,* 2003, 1039.

[34] Cass. Civ. (Cassation Civile), 6 March 1945, *D* 1945.1.217.

At the same time, French case law even affirmed the contractual liability of the blood transfusion centres, for damages arising out of contaminated blood, stating that the hospital had made a contract with the blood transfusion centres for the benefit of the patient, and that contract imposed an *obligation de résultat* concerning the safety of the blood.[35] The result was that the blood transfusion centres were held liable using a fictious finding of a contract in favour of a third party, the damaged patient, and without proof of either fault or defect in the blood and, moreover, with no defence that the infection in the blood was caused by circumstances beyond their control[36].

This strict approach of French case law to blood transfusion centres liability was lately applied to what is called the '*affaire du sang contaminé'*. The *Chambre Civile de la Cour de Cassation*, in its decisions 12 April 1995[37] and 9 July 1996,[38] held that the blood transfusion centres were liable for the damages arising out of blood infected with HIV, as they were under an *obligation de sécurité de résultat* and so bound to supply products free from defects and could escape their liability only showing the existence of an external cause of the injuries.

The liability of the blood transfusion centres could not be excluded by the fact that the defect was hidden, or even not detectable.

The Same Cour de Cassation even held, on the other side, that the duties of the clinics were *obligation de prudence et diligence*. As a consequence the appealed Courts had to investigate if the single hospital had the chance to check the quality of the blood received from the blood transfusion centres, before stating its liability.

In the same lapse of time the Assemblée of the Conseil d'Etat, the French administrative Court, was asked to judge some 600 claims of liability against blood transfusion centres and public hospitals for HIV infections arising out of contaminated blood. That Court agreed with the approach of the Cour de Cassation, affirming that the blood transfusion centres were liable independently from fault, while the hospitals could be held liable only if their fault was proved, as they only supplied the blood.[39]

Compliant to these decisions, the following French case law has always held the Etablissements Français du Sang, that succeed to the blood transfusion centres,

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[35] Cass. Civ., 17 December 1954, *JCP* 1955.II.8490 with note by R. SAVATIER, *D* 1955.269, with note by R. RODIER; App. Paris. (Appel Paris), 28 November 1991, *D* 1992.85, with note by A. DORSNER-DOLIVET; *JPC* 1992.II.21797, with note by M. HARICHAUX.

[36] *cfr.* S. WHITTAKER, *Liability for Products, English Law, French Law, and European Harmonization*, Oxford University Press, Oxford, 2005, 149-150.

[37] Cass. Civ., 1re, 12 April 1995, 2 cases, *JCP* 1995.II.22467, with note by P. JOURDAIN. In general, on the tort liability for personal damages in France, see: Y. LAMBERT-FAIVRE, *Droit du dommage corporel, systèmes d'indemnisation,* 4e ed., Paris, 2000.

[38] Cass. Civ., 1re, 9 July 1996, 3 cases, *D*, 1996, 610, with note by Y. LAMBERT-FAIVRE.

[39] CE (Conseil d'Etat), 26 May 1995, 3 cases, *Leb.* 221, AJDA *(Actualité Juridique Droit Administratif)* 1995.577-78 with note by J.H. STAHL and D. CHAVAUX, *JCP* 1995.II.22468, with note by J. MOREAU.

liable for the contaminated blood damages, and excluded the liability of the hospitals and clinics that had only administered the contaminated blood.[40]

The evidence of the causation is assumed to be proved when the petitioner demonstrates that the contamination was the consequence of blood or blood products transfusions and not the result of his behaviours, while the defendant must prove the products he supplied were faultless.[41]

The causation between the blood products transfusions and the injuries is even presumed by article 102 of the Loi 2002-303 of 4 March 2002, concerning compensation of Hepatitis C infections that are the consequence of blood transfusions dating before the law, and by Loi n° 91-1406 of 31 December 1991, that established a special system of statutory compensation awards in cases of HIV infections.

This latter law always entitles the victims to claim judicial compensation, in tort or in contract, for items of damages not provided for by the fund.[42]

French case law not only stated the liability of the blood transfusion centres but even, as in the discussed Italian case, of the State. Actually, the case is under many profiles similar to the Italian case.

In fact the Conseil d'Etat in its decision issued on 9 April 1993[43] affirmed the liability of the State, as responsible for the Ministry of Health, because the latter had failed in the exercise of his legal powers of control over the safety of the blood distributed by the blood transfusion centres.

The decision of the Court was based on the application of the requirement of *faulte simple* (while as a rule to affirm the State liability is required the existence of a *faulte lourde*) while the existence of the causation was affirmed on the basis of the facts of the reception of blood and the HIV-positive diagnosis. Moreover, the same Court rejected the defence of the State, affirming its liability could not be heavier that its proper share of responsibility.

Policy arguments were certainly at the base of the decision, as the plaintiffs would otherwise be left only partially compensated, but it is undisputed that even political and symbolic needs played their part in the Court reasoning.[44]

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[40] Cass. Civ., 1re, 13 November 1996, *D.* 1996, *Informations rapides*, 268 ; Conseil d'Etat, 5e et 3e s.-sect. réun., 30 July 1997, *D.* 1999, *Sommaires commentés,* p. 57.

[41] Cass. Civ., 1re, 18 June 2002, n° 01-00.381, *D.*, 2002, Informations rapides, 2307; Cass. Civ., 1re, 28 March 2000, *Bull. civ.(Bulletin des arrêts de la Cour de Cassation - Chambres Civiles)* I, n° 108 ; *D.*-, 2000, IR p. 130; Cass. Civ., 1re, 23 November 1999, in *Bull. civ*. I, n° 324 ; *D.* 1999, IR p. 280.

[42] Cass. Civ., 1re, 9 July 1996, cit. ftn. (38). *cfr.* CANNARSA, *La responsabilité du fait des produits défectueux,* Giuffré, Milano, 2005, p 311.

[43] CE, 9 April 1993, *Req. no.* 138652, *D* 1993.312 with conclusion by M. LÉGAL, observations by C. MAÜGUÉ, L. TOUVET, *AJDA* 1993 Chron. 344.

[44] For a through analysis of the case, see S. WHITTAKER, *Liability for Products, English Law, French Law, and European Harmonization*, cit. ftn. (36) 315-319, pointing out the political and symbolic importance of the Court decision, as well as legal, in the atmosphere surrounding the *affaire de sang contaminé.* For an analysis of the criminal decisions see the same author, 394-401.

With reference to English case law on the issue, the leading case is certainly *A and Others* v. *The National Blood Authority and Others.*[45] The case involved 114 persons infected by Hepatitis C following blood transfusions of contaminated blood, which acted for compensation against the National Blood Authority, the English authority charged of blood and blood products production.

Both parties agreed that blood constituted a product under EC Directive 85/374,[46] and that NBA was producer of the blood and blood products.

The High Court held NBA liable for the compensation, not in the tort of negligence but on the basis of liability arising under the *Consumer Protection Act,* the English law of implementation of the EC Directive 85/374, as the transfusions that caused the damage were made after its coming into force.

The High Court, following the provisions of article 6 of the Directive, took into consideration the circumstances of the case,[47] and affirmed that the test to be applied to the case was that of the legitimate expectations of the public concerning the safety of the product, and not that of the safety of the product itself.[48]

It added that even if the risk of the products were known by doctors, they were not known by the persons who received transfusions of contaminated blood or blood products. Consequently, the patients didn't expect the risks of the blood products.[49]

As the risks of the products were know before they were put into circulation, the Court considered inapplicable article 7(e) of the Directive, providing the

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[45] *A and Others* v. *The National Blood Authority and Others* [2001] 3 All ER *(The All England Law Reports)* 289, 2001 WL *(Westlaw)* 239806, [2001] Lloyd's Rep. Med. 187, 60 BMLR1, Times, April 4, 2001, Daily Telegraph. April 3, 2001. Comments: HODGES C. 'Compensating Patients' in *L.Q.R. (Law Quarterly Review) 2001, 117(OCT), 528-532;* G. HOWELLS and M. MILDRED, in 'Infected Blood: Defect and Discoverability. A First exposition of the EC Product Liability Directive, *MLR (Modern Law Review)* 2002, 95-106; A. KABISHI, 'Thalidomide Revisited: Relevance of the Hepatitis C Litigation', *B.L.R. (Business Law Review)*, 115-117; J.M. WILLIAMS 'Product Liability – Hepatitis C Litigation' in *J.P.I.Law (Journal of Personal Injury Law)* 2001, 3, 238-246; S. WHITTAKER, *Liability for Products, English Law, French Law, and European Harmonization*, cit. ftn. (36) especially 486-492.

[46] See GRUBB A. and PEARL D.S., *Blood Testing, AIDS and DNA Profiling*, 1990, Jordan & Sons, Bristol, 1990, pp. 135–142 for a discussion of the question of natural products, such as biological ones, constituting products under the CEE Directive.

[47] Even if the test may seem easy to apply, it's actually of difficult practical application. On this issue, see: J. STAPLETON, *Product Liability,* London, 1994, p. 236 ss.

[48] On this issue, see S. WILLIAMSON, 'Compensation for Infected Blood Products: A and others v National Blood Authority and Another', vol 7.5 electronic journal of comparative law, (December 2003), <*www.ejcl.org/ejcl/75/art75-5.html*>, comparing previous cases that had applied the provisions of CPA.

The consumer expectation test used in the decision is criticized in J. A. HENDERSON and A. D. TWERSKI, 'What Europe, Japan and Other Countries Can Learn from the New American Restatement of Products Liability', 34 *Texas International Law Journal* 1, 12 (1999).

[49] G. HOWELLS and S. WEATHERILL, *Consumer Protection Law*, Ashgate, Aldershot, 2005, 243, affirmed that the standard given by Burton J '*is not actually based on what consumers actually expect, but rather on what they should be entitled to expect'.*

exemption of the producer liability if the state of scientific and technical knowledge when the product was marketed was such that the defect could not be discovered.

The Court affirmed that that exemption could be applied only to cases of unknown defects, and not to cases in which the producer was aware of the risks but didn't stop supplying the products just because, and despite the fact that, he was not able to locate the defective ones. It stated that that exemption could be applied only if a defect unknown before emerged, not when the producer was aware of the risks but nevertheless he didn't stop supplying the defective products only because, or notwithstanding the fact, he was not able to detect the defective ones.

It is important to stress that the High Court didn't take in consideration the conduct of the producer, deeming irrelevant if it would have been possible, practicable, costly or burdensome to avoid the harmful characteristic arising in the product. As a consequence, it excluded from consideration of legitimate consumers' expectations the issue of avoidability of the damage, which he regarded as being relevant only to the question of development risks. Therefore, the Court expressly refused any fault-based consideration in interpreting the law of implementation, relying on the purpose of the Directive as revealed in its recitals.[50]

This approach is not new to European Courts, and the exclusion of the relevance of the conduct of the producer can be found in other decisions, such as the '*German Bottle Case*'[51] or in a Dutch case concerning the claim against the producer for the compensation of HIV infection arising out of a contaminated blood transfusion.[52]

Lastly, the High Court asserted that even if the defendant had a statutory obligation to supply the product and therefore would not have been in a position to cease supply of the product, and even if it was a public authority or a no profit authority, its duties were the same of a commercial producer.[53] Therefore, the defendant had to face its liability for damages, contracting insurances or by other means.

So, the High Court held the liability of NBA for the harm arising out of transfusions of infected blood or blood products for the period in which tests permitting to avoid or at least reduce the risk of virus transmission already existed and were used in some countries, as France and USA.[54]

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[50] See on the issue P. GILIKER, 'Strict Liability for Defective Products: The Ongoing Debate', in *B.L.R.*, 2003, 87-90, 88. G. HOWELLS and M. MILDRED, op. cit. ftn (44) suggested that the solution given by Burton J didn't provide any tangible standard for future cases.

[51] (9 May 1995) NJW 1995, 2162, Bundesgerichtshof.

[52] Scholten v Foundation Sanquin of Blood Supply, 3 February 1999, unreported, County Court of Amsterdam, discussed by Burton J at Para 44.

[53] Shortly after, the European Court of Justice held in the case *Veedfald v Arhus Amtskommune,* C-203/99, [2001] ECR I-3569, that the facts that products are manufactured for a service for which the patient has not paid and which is financed with public funds '*cannot detract from the economic and business character of that manufacture'*.

Any civil decision on HIV infection is absent in England, as a settlement was made between the 962 haemophiliacs and they dependant that claimed damages for the HIV contracted in consequence of blood products supplied by the National Health Service and the many defendant public authorities and bodies. Even if the Government took part in the settlement it denied any negligence,[55] but the settlement gave way to the creation of a special fund for the compensation of certain victims of blood products.

6. Conclusion

It is evident that with its decision issued on 31 May 2005 the Italian Corte di Cassazione acted to protect the numberless persons damaged by a negligent public authority, that didn't observe its statutory obligations of protection.

In the short time that decision will certainly permit the compensation of the many persons damaged by infective blood or blood products transfusions, and in the long time it probably will even permit to enlarge the number of cases of compensation for damages following omissions by public authorities to comply statutory obligations of protection.

The Court was clearly guided in its reasoning by a protective policy, that determined the Court to apply, failing the application of the EC rules on product damages, the general rule on tort liability and to substantially reverse the burden of proof concerning the existence of a negligent omission of the Ministry of Health to its statutory duties.

It is important to point out how the three different case law (the English, the French and the Italian), notwithstanding the different rules applied to the cases and the related different issues consequently faced, substantially converge in their final statements, holding liable for the compensation the public authorities directly or indirectly charged of the production and marketing of blood and blood products.

Actually, as in cases of damages consequent to defective blood and blood products it may be often difficult for the actors to prove the liability of the negligent defendant, it is evident the common effort of those Courts to improve the chances of compensation of the damaged persons, pursuing a policy of protection of the weaker subjects.

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[54] On the issue of the use of comparative law in this case see: M. BROOKE, I. FORRESTER, N. UNDERHILL and M. BURTON, 'The use of comparative law in A & Others v National Blood Authority', in *Product Liability in Comparative Perspective*, D. FAIRGRIEVE (ed.), Cambridge University Press, Cambridge, 2005, pp. 13–41.

[55] The settlement was approved by the High Court in June 1991, in *The Times*, 11 June 1991, 3. On that settlement, also see *The Times*, 12 December 1990, *The Times*, 30 January 1990, 6 and S. WHITTAKER, *Liability for Products, English Law, French Law, and European Harmonization*, cit. ftn. (36) 356-360.