Hepatitis and Development Risks

Liability of the laboratory that sold blood infected with the HCV (SSC, 1st, October 5, 1999) and of the Public Health Administration that employs it (SSC, 3rd, May 31, 1999)

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On the HCV infection and liability, see ***Hepatitis C*** in **InDret**

Abstract

Last fall, for the first time, the Spanish Supreme Court (SSC Decision on 5.10.1999) sentenced a pharmaceutical laboratory to provide compensation of 300,506 euros to a patient who received blood sold by the lab in 1986 and which infected him with the hepatitis C virus (HCV).

Should this position prevail in future decisions, pharmaceutical laboratories would be made liable for development risks in defective products sold before July 8, 1994. This date marks the introduction of Law 22/1994, July 6, *of liability for damage caused by defective products*.

A few months earlier, the SSC, 3rd, 31.5.1999, decided a case involving the liability of the public health administration. The claim was based on an infection of the HCV in 1975: although the Court did not reject that an exception for development risks - introduced expressly in art. 141.1. of Law 30/1992, by Law 4/1999- could be claimed, it shifted the burden of proof to the administration being sued. Nevertheless, a particular vote heavily criticized the doctrine supported by the majority.

In this paper, we question whether current legislation is reasonable, based on the following factors. First, it impedes the invocation by pharmaceutical laboratories of an exception for development risks for accidents that occurred after the introduction of Law 22/1994. Second, on the other hand, it allows the State to do so. Third, the State then passed a law, which led to another law being introduced, conceding social assistance to a restricted group of hepatitis C patients infected in public health centers, namely, those who suffer from hemophilia or other congenital clot conditions. Finally, not everyone is guaranteed a complete compensation for harm suffered.

1. The HCV

The HCV is a serious disease of the liver. The virus was identified between the end of 1988 and the beginning if 1989. It was previously known as “hepatitis no A no B.”

Presently, there is no vaccine to prevent the HCV. The virus may appear early, within the first three weeks after infection, or remain latent during decades and become chronic. The first test to detect the presence of HCV antibodies in the blood was performed in May of 1990 in the United States.

In Spain, the Order of the *Ministerio de Sanidad y Consumo* (Consumer Affairs and Health Ministry) on 3.10.1990, established a requirement to perform tests in order to detect the HCV in blood and plasma. Currently, the *Real Decreto* 1854/1993 (22.10.1993) sets the technical standards and minimal conditions for blood donations and blood banks.

Several Regional Governments required the test in question before October of 1990, and as a result, it was under state regulation: Catalonia (15.3.1990) and Valencia (1.6.1990).

The following are the most common ways of contracting hepatitis C, in order of importance:

a) Via contact with infected blood. There are many situations in which one is exposed to blood: transfusions, products derived from blood, blood dialysis, sharing needles, tattoos, piercings, or simply, in work-related accidents of health professionals.

b) Sexual relations and family life. The transmission of the HCV through sexual relations and family life is possible but not very likely.

c) Prenatal. A woman infected by the HCV transmits the virus antibodies to her child during the period of gestation. However, the child rarely develops the disease.

There is only a small likelihood of becoming infected with the HCV from a blood transfusion or treatment with products derived from blood (1 of every 400,000 transfusions). However, neither treatments with products derived from blood, nor other treatments are the principal cause of the HCV infection. This is evident because the number of infections continues to increase: in Spain in 1998, around 1,100 new cases were identified, whereas in 1997, there were only around 750. Along the same lines, the Instituto de Salud Carlos III (health institute) presented in its *Boletín Epidemiológico Semanal* (vol. 6, num. 17, 1998) that in 1992 the various hepatitis viruses caused 176 deaths and that during the period 1992-94, hepatitis caused 1,74% of all deaths related to infectious diseases. This percentage is almost three times more than the 0,60% that corresponded to the period of 1980-82.

2. Spanish Supreme Court Decision, First Chamber, 5.10.1999

2.1 Facts

The plaintiff, Joaquín Orera Hernández, was medically treated in 1986 with blood plasma (*fibrinógeno*) that was infected with the HCV and he contracted the disease. In 1993, Mr. Orera sued the laboratory that sold the plasma (ICN-Hubber, S.A.) for a damage award of 2,614,403 euros.

2.2 First Instance Court Decision, num. 14 of Zaragoza, 16.2.1994

The plaintiff based his claim on art. 1902 of the Spanish Civil Code. The company being sued defended itself as follows:

i) Statute of Limitations: the plaintiff was infected in 1986 and became aware of some hepatitis-related conditions during that same year. The suit was filed seven years later, long after the expiration of the one-year legal term.

ii) Lack of passive standing: the blood bank that provided the laboratory with the plasma and the doctor that prescribed the product derived from blood, should be liable, and not the laboratory.

iii) Need to sue all tortfeasors: the blood bank, *Administración sanitaria* (health administration), INSALUD, insurance companies, and the doctor, who prescribed the blood plasma, should also have been sued.

iv) Lack of a causal link and any kind of negligence: in 1986, it was impossible to detect the presence of the HCV in blood.

Judge Jesús Ignacio Pérez Burred rejected the claim against the company. Specifically, the judge rejected the defendant's first three allegations and accepted the fourth one:

Ad i) The Statute of Limitations runs from the point in time in which it is possible to recognize the harm and its consequences (art. 1969 CC). The plaintiff was informed of the official and definitive diagnosis of his chronic disease in the beginning of 1992, less than a year before making the claim (F. de D. 2º).

Ad ii) The fault or negligence of the blood bank that provided the plasma that was used to elaborate the product derived from blood, or of the doctor that prescribed it, does not exclude the laboratory from liability (F. de D. 3º).

Ad iii) In Tort law, the liability of multiple tortfeasors is joint and several (art. 1144 of the CC) and therefore, there is no need to sue all tortfeasors (F. de D. 4º).

Ad iv) On the issue of a causal link, as well as, of objective and subjective (fault) imputation, Judge Pérez Burred found the following:

a) The brief period of 11 days, between surgery and the first appearance of pathological hepatitis symptoms, is compatible with the average incubation period for hepatitis C, between 4 and 6 weeks.

b) Other possible causes of infection could be pointed out, although it was not demonstrated during the trial that the patient participated in practices associated with the risk of the HCV infection.

c) Both the manufacturer's warnings on the product container of the risk of hepatitis C infection, and the medical community's knowledge of a generic risk, pointed clearly to the path of infection in question (F. de D. 5º).

d) The HCV was isolated and identified for the first time in the U.S.A. in 1988. Previously, only the existence of other forms of the virus (hepatitis no A and no B) were known. Second, serological tests for detecting the HCV were first performed in 1990. Previously, the only procedure used to prevent infection involved selection criteria for blood donors, which excluded those who belonged to one of the risk categories empirically associated with the disease. Given these circumstances, the negligence-based liability established in art. 1902 CC could not be proven, nor the exceptional and quasi-objective liability of art. 28 of Law 26/1984, July 26, *General para la Defensa de los Consumidores y Usuarios* (consumer protection; LGDCU). The accident may be considered fortuitous because even if the manufacturer "could have foreseen the existence of a risk (infection of the HCV), it was not possible... to avoid it, even

with the extreme care and diligence that the nature of the product required" (F. de D. 6º and 7º).

2.3 The Zaragoza Court of Appeals' Decision, Fourth Section, 17.1.95

The Zaragoza Court of Appeals' Decision, Fourth Section, on 17.1.95 (Judge: José Javier Solchaga Loitegui) upheld the prior ruling.

In the appeal, the defendant invoked articles 43.1 and 51 of the Spanish Constitution (SC) of 1978, which respectively, recognize the right to protection of health and require the State to guarantee consumer protection. In addition, art. 28 LGDCU was invoked, which establishes a strict liability rule for harm caused to consumers by goods and services.

For the Court of Appeals, the art. 28 LGDCU established a rule of strict liability but it does not include "development risks, in other words, those defects that at the time of production or sale of the good... could not be discovered based on the information available" (F. de D. 7º). It also found that the exception for development risks, established by Law 22/1994 and the Directive of 1985, does not apply because the facts of the case were produced before it took effect.

2.4 Spanish Supreme Court Decision, First Chamber, 5.10.1999

The plaintiff appealed to the SSC and claimed, among other grounds, violation of arts. 43 and 51 of the SC with regard to arts. 25, 26 and 28 of LGDCU.

Judge Xavier O'Callaghan Muñoz decided in favor of the plaintiff. He found that art. 28 LGDCU applied to the case and sentenced the defendant to provide compensation of 300,506 euros.

2.5 Legal Doctrine?

The Decision did not include information on the plasma's date of production or on the medical treatments. However, this information may be found in the Instance Court's Decision. Therefore, a reader of the SSC Decision lacks the information necessary to assess the value of the legal doctrine's limits, which the SSC could have contributed to establish. In particular, the Decision does not clarify the boundaries of liability for development risks.

> Information regarding the relevant dates is only available to the reader of the SSC Decision (5.10.1999) in its F. de D. 2º. This source states that both Directive 85/374/CEE and Law 22/1994 *"[are] inapplicable to the present case."* Law 22/1994 does not apply to cases that involve harm caused by defective products sold before the law was introduced on July 8, 1994. Due to the literal sense of the SSC Decision, it may be concluded that the product was sold before the introduction of the law in question. Nevertheless, we know based on the Instance Court's Decision that the surgery took place on March 3, 1986. Additionally, the First Instance Court accepted the fact as proven -the Court of Appeals implicitly accepted it- that the product was sold before this date and was defective and contaminated with the virus.

2.6 Applicable law: articles 28 of the General Law on Consumer Protection and 40 of the Law of Medicine

According to the facts mentioned above, which are considered to be proven by the Decision, art. 28 LGDCU would apply to the case, along with art. 40 of Law 25/1990, December 20, of Medical Drugs (LMed). According to these texts:

> Art. 28 LGDCU: "1. Despite the previous articles, a manufacturer is liable for harm caused by its goods or services that were used and consumed properly, either according to the product's nature or an established rule. A manufacturer must guarantee that its product maintains a certain level of purity, efficiency and security, based on objective criteria. Additionally, technical, professional and systematic quality controls must be performed until the product is in a proper condition to be used by a consumer. 2. The following products and services are included in this liability category: foodstuffs, hygiene, cleaning, cosmetics, pharmaceuticals, health services, gas, electricity, electrodomestics, elevators, public transportation, motor vehicles, toys and children's products. 3. Without contradicting other legal provisions, liability awards based on this article would be limited to 500 million pesetas. This amount should be periodically revised and updated by the Government, with regard to the fluctuation of consumer price indexes."

> Art. 40 LMed: "*Medical substances derived from blood plasma and other human fluids, glands and tissue.* 1. The derivatives of blood plasma and other human fluids, glands and tissues, when used for therapeutical purposes, are considered medical drugs and are subject to the rules outlined in this Law, in addition to the exceptions established based on the particular nature and characteristics of each case. 2. As a rule, -blood, plasma, and its derivatives-, as well as, -other human fluids, glands, and tissue-, should be provided by identified donors and regulated by authorized centers. The centers must respect the measures available to prevent the transmission of infectious diseases."

2.7 Product, defect, harm and causal link: development risks of pharmaceutical products

We have observed that the SSC Decision fully accepted the facts presented in the two Instance Court Decisions (that were in agreement) as proven. In particular, they accepted that: the defendant produced the product in question, it was defective, and the defect was the cause of the patient's serious bodily injury. Since the SC accepted these facts without further question, the Decision does not discuss the requirements we have mentioned.

The discrepancy between the Decisions of the SSC and Court of Appeals, is based on the *Fundamento de Derecho 2º*. The Court of Appeals decided that a causal link, objective imputation of the defendant, and his/her negligent or fault-based actions must be established in order to hold him/her liable for a defective product. However, we have also noted that the Court of Appeals' Decision did not conceptually distinguish between the three criteria. Consequently, the SSC retraced the Court of Appeals' steps. The SSC also considered the three topics -causal link, objective imputation and fault- but in a very superficial way. The only reference made in the SSC Decision is that according to article 28.2 LGDCU, a manufacturer's liability is strictly objective and therefore, the laboratory is liable:

> "Article 28 establishes liability for *harm caused despite the correct use and consumption of goods and services*, with certain limitations outlined in section 1. Section 2, nevertheless, adds that a strict liability rule applies to *pharmaceutical products in all cases.* Pharmaceutical and other products are subjected to the same rule. They account for a strict liability precedent explicitly proclaimed by the *Directiva del Consejo*, 85/374/CEE, July 25, subsequently extended by Law 22/1994, July 6, on strict liability for harm caused by defective products; however, both norms are inapplicable to the present case" (F. de Dº 2º).

The Court of Appeals combined the three previous criteria and the SSC settled them in one paragraph. However, they probably should not be analyzed together. The causal link is clear, if we accept the First Instance Court's presentation of the proven facts, and reject the objection of the short incubation period of the disease. We may dispute the requirement of adequate strict liability, given that the HCV had neither been identified before the product was put on the market, nor before the date of treatment. Therefore, it can be assumed that not even the most diligently informed observer could have foreseen the damage, in other words, the possible infection of a disease. It could also be argued that the possibility existed to test for hepatitis no A no B. Finally, even those who distinguish between objective imputation and fault, and refer to the latter as subjective imputation (a topic that InDret questions, but will not be covered in this paper), it seems clear that the defendant did not act negligently, given the information available at the time the product was sold.

In any case, the succinct resolution of the SSC implies that the strict liability taken from article 28 LGDCU, as presently interpreted by the First Chamber of the SSC, includes liability for development risks.

The exception of manufacturer's from development risks is currently regulated in Spanish Law by art. 6 of Law 22/1994:

> Art. 6. *Reasons for exclusion from liability:*
>
> 1. A manufacturer or importer will not be liable if it proves that:
>
> e) When the product was sold the scientific and technical information available was insufficient to discover the defect.
>
> 3. In the case of medicines and foodstuffs for human consumption, those held liable according to this Law may not invoke the cause of dismissal in draft e) of section 1 of this article.

The Decision does not establish a legal rule on the subject of causation but it does with regard to the distinction between strict and no-fault liability. It also applies a standard of strict liability to cases of hepatitis C infection from blood plasma transfusions that are infected with the HCV and were carried out between July 25, 1984 (when the LGDCU took effect) and July 8, 1994 (when Law 22/1994 took effect). We can assume that the current First Chamber judges will continue to uphold the current legal criterion on the inapplicability of an exception for development risks for defective pharmaceutical products sold before the introduction of Law 22/1994.

The Decision in question applied art. 28 of LGDCU to a case of a viral infection from blood derived products that occurred after the introduction of this Law. It is now a settled jurisprudence:

> - SSC, 1st, 10.11.1999 (Judge: Ignacio Sierra Gil de la Cuesta). The case involved a patient who died after contracting HIV and HCV from a transfusion that was performed in August 1986. The widow and children of the deceased sued the *Servicio Andaluz de la Salud* (Andalucian health service) for 601,012 euros. The SSC rejected the Court of Appeals' Decision and upheld that of the Instance Court, which awarded the plaintiffs 120,202 euros.

- SSC, 1st, 9.3.1999 (Judge: Román García Varela). The case involved an infection of the HCV from a transfusion carried out in October of 1989 in a public hospital. The JPI rejected the claim but the AP and the SSC sentenced INSALUD to provide 36,061 euros as compensation.

- SSC, 1st, 28.12.1998 (Judge: Ignacio Sierra Gil de la Cuesta). The case involved a pregnant woman who was infected with HIV from a transfusion performed on 22.9.1984. The SSC rejected the Decisions of the JPI and the AP, and provided the victim's widower with a damage award of 90,152 euros.

- SSC, 1st, 11.2.1998 (Judge: Antonio Gullón Ballesteros). Prior to 1992, the plaintiff was infected with HIV from an inoculation and sued INSALUD, the *Ministerio de Sanidad* (health ministry) and the doctor for an amount of 601,012 euros. The JPI sentenced INSALUD to provide an award of 60,101 euros, in addition to another 150,253 euros if the symptoms of the disease appeared. The Court of Appeals' Decision sentenced the defendant to provide a single award of 72,121 euros, which was upheld by the SSC.

Nevertheless, the following Decision did not follow the same line of jurisprudence as above. (CA of Barcelona, Section 16, on 24.4.1998. Judge: María Núria Zamora Pérez). The case involved a patient who was infected with HIV from a transfusion received during surgery. The claim was rejected because all of the required and available tests were performed, and the LGDCU did not establish strict liability of the health services. Nevertheless, this Decision may be rejected in the appeal, following the same fate as the Decision of the Court of Appeals of Zaragoza.

2.8 Valuation of the damage award

The Decision provided the plaintiff with a damage award of 300,506 euros because he/she was infected with the HCV. The award was divided as follows: 210,354 euros for personal injury and 90,152 for pain and suffering. The judges calculated the amount "based on discretional criteria and a comparison to similar and more serious cases" (F. de D. 3º).

This damage award was very high in comparison to the amounts established by the *Real Decreto Ley* of May 28, 1993, *of assistance offered to those infected with HIV as a result of treatment received in the public health system* (Specifically, art. 2 establishes the amount of 60,101 euros and monthly assistance of variable amounts and duration depending on an applicant's circumstances). Also, in comparison to the amounts awarded by Courts in 1999 for HIV infection cases (330,557 euros: SSC, 4th; 5.5.1999 and STSJ Madrid, Sala Contencioso-Administrativa; 17.3.1999; 270,455 euros: SAP Alicante, Civil, 24.2.1999 [we should mention that the award makes an allowance for another 144,243 euros if the disease develops]; or 120,202 euros: SSC, 1st, 10.11.1999); and the HCV (30,051 euros: STS, 3rd, 31.5.1999 and STSJ Navarra, 4th, 9.6.1999; or 36,061 euros: SSC, 1st, 9.3.1999).

2.9 Legal limitation of liability according to art. 28.3 of *Ley General para la Defensa de los Consumidores y Usuarios* (law for the protection of consumers) of 3,005,061 euros

The third section of article 28 LGDCU limits the monetary value of liability derived from its application to 3,005,061 euros. However, the Decision in question does not address this point.

The cap applies to cases such as that of the Decision in question. Nevertheless, the following restrictions should be followed:

a) The State should periodically revise and update this liability limit, taking into account the variation of consumer price indexes. Although we cannot be certain that the State has presently fulfilled this obligation, an update may be passed soon and it could be carried out with retroactive effect. However, it is not enough to reject it based on the legal mandate.

b) Art. 11 of Law 22/1994 establishes a similar cap but at a higher amount (63,106,271 euros) for strict liability cases of manufacturers, which fall under its application area. It specifies that the liability cap applies to cases of "death and personal injury caused by identical products that present the same defect." On the other hand, neither this limitation nor a similar one is found in art. 28 LGDCU, which generically limits itself to a liability cap of 3,005,061 euros for "the types of liability found in this article." In practice, we could argue that the limitation criterion of Law 22/1994 also applies to the cases in question.

c) The global liability cap from art. 28 LGDCU is established "[w]ithout going against anything established in other legal provisions." In other words, it doesn't include other liabilities, such as that based on an application of articles 109 and following of the Penal Code of 1995, on civil liability derived from a criminal offence.

3. Spanish Supreme Court Decision, Third Chamber, 31.5.1999

We have found that a manufacturer is strictly liable for development risks before and after the application of the Directive. However, there is probably a different quantitative liability limit for each case.

What standard of liability would apply if the defendant were a public administration, instead of an individual that falls into the legal category of private law? The answer is not easy. The Law 4/1999, January 13, of the modification of Law 30/1992, of *Régimen Jurídico de las Administraciones Públicas y del Procedimiento Administrativo Común* has protected the Spanish Public Administrations from liability for development risks and they may claim an exception under all circumstances.

According to art. 141.1 of Law 30/1992, modified by art. 1.37 of the cited Law 4/1999:

> "Damages will only be awarded for injuries that the plaintiff has no duty to bear. Damage that results from acts or circumstances, which the scientific and technical information available could not foresee or prevent, do not qualify for compensation. These guidelines do not exclude the possibility of social or economic assistance established by law for such cases."

The SSC, 3rd, 31.5.1999 had already referred to the issue of development risks in a case that involved a hepatitis C infection in 1975 -13 years before the HCV was identified – resulting from a blood transfusion the plaintiff received during surgery at a public hospital.

3.1 Facts

The plaintiff underwent surgery after having an accident at work on December 25, 1975. He received a blood transfusion during surgery, and in 1978 he was diagnosed with a chronic and persistent hepatitis (HbsAg). On March 9 of 1993, the diagnosis was specified as the HCV.

The victim claimed from INSALUD on 15.11.1993 an award of 150,253 euros, which was implicitly rejected by INSALUD. The victim filed suit before an administrative Court.

3.2 High Court of Cantabria Decision, Administrative Chamber, 24.1.1995

The HC of Cantabria, in a Decision of 24.1.1995, rejected the claim because it considered that the time limit of a year should have begun with the HC of Cantabria Decision, Social Chamber, on 16.10.1990, in which the plaintiff was declared as being in complete incapacity to perform his job.

3.3 Spanish Supreme Court Decision, Third Chamber, 31.5.1999

The SSC Decision found in favor of the plaintiff and sentenced INSALUD to provide him with an award of 30,051 euros in addition to the legal fees incurred after the HC Decision.

The Supreme Court found that:

1. The claim had been timely because the starting point for computing the one-year period of liability claims against the Public administration should have begun on the date of the final diagnosis on March 7, 1993, in other words, 8 months before the claim that instigated the appeal (F. de D. 4º). We remind you that art. 40.3 of the Decree on July 26, 1957, *del Texto Refundido de la Ley de Régimen Jurídico de la Administración del Estado*, states that: "[I]n all cases, the right to appeal expires one year after the harmful event (which is the subject of the claim) takes place."

2. Development risks do not qualify as "force majeure": to this effect "the cause of an injury," wrote Judge Sr. Francisco González Navarro, "has to be far removed from the activity's inherent risk" (F. de D. 5º).

3. The regulation on an exception for development risks established by the new art. 141.1 of Law 30/1992, after its modification by Law 4/1999, is not directly applicable to the case. However, it is indirectly applicable, as explained by the Judge, because "what [the new text] does" is "*positivizar"* (meaning: to convert to positive law, or 'completed' and written law) a latent principle (in other words: hidden, in which latent –contrary to some beliefs- is not derived from *latir*, rather from the Latin term 'latere', which means 'to hide') in the prior regulation" (F. de D. 5º, letter B). Additionally, in all cases, "it is not enough to invoke the lack of scientific knowledge on the subject in question, rather it is necessary that this insufficient state of science is proven, a test that –with a strict application of the burden of proof rules- would have to be performed by the State, which until now has not been attempted."

Nevertheless, the Decision (F. de D. 4º) records the year of the HCV identification as 1988, according to the information gathered by the Administration being sued, when implicitly acknowledging the causal link between the blood transfusion administered during surgery and the disease. Perhaps due to this point and the apparent contradiction, which assumes the acceptance and denial of the same proven facts, the judges (Peces Morate and Sieira Míguez) cast a dissenting vote. It declares that the plaintiff's claim should have been rejected for the following reasons:

1. The burden of proving what scientific and technical information was available at the time of the harm is on the Governmental defendant side, but this burden is irrelevant when the facts are evident or obvious, such as in this case. The plaintiff was infected with the HCV thirteen years before its diagnosis was possible. Given that at the time of the transfusion, it was impossible to test whether the blood was contaminated, the possibility of infection was a risk that the patient was forced to accept (F. de D. 4º y 5º).

2. Based on art. 141.1 of Law 30/1992, in the prior and current editions (modified by Law 4/1999) the State is not legally bound to compensate damage that the injured person is obligated to accept. Otherwise, "the State would become a universal insurance provider for all social risks, which is not harmonious with the meaning of tort liability, however strict it might be" (F. de D. 3º).

4. Other cases involving the liability of pharmaceutical laboratories for blood transfusions infected with the HCV or HIV

The SSC, 1st, 5.10.1999, for the first time, held a pharmaceutical laboratory liable for the defects in its products derived from blood. Also for the first time, the Court established a very strict liability standard that denies claims for an exception based on development risks in cases that took place before the introduction of Law 22/1994.

There is a history of cases involving the AIDS virus (HIV) infection, which found against laboratories. For example, the following case (CA of Baleares, Civil, 4.4.1995) involved a patient of a public hospital who was infected with AIDS as a result of a transfusion received from the blood product Bebulin, manufactured by the Laboratories Landerlan in October of 1984. The Court of Appeals' Decision upheld the Instance Court's Decision that sentenced INSALUD and the laboratory to provide 210,354 euros.

5. Final evaluation and a proposal

On the subject of product liability for development risks, the pharmaceutical industry may be held liable to provide up to 3,005,061 euros for harm caused before 1994 (art. 28.3 LGDCU) and an additional 63,106,271 euros for harm caused after the introduction of Law 22/1994 (art. 11 Law 22/1994). Given that development risks are not foreseeable by definition, a strict liability with caps applies. In contrast, according to the general Civil law (and the Penal Code when applicable), liability is for malice or fault, but is uncapped. Obviously, the double standard cannot function well in practice, especially in cases involving serious harm: in these cases, an increase of due care, or even a presumption of fault or lax imputation criteria, is foreseeable. Along

these lines, we should refer to the arguments used in the SSC, Second Chamber, 26.9.97, which found the State liable (on the basis of "respondeat superior") in the case of those harmed by colza oil. This causes legal uncertainty and the final result is paradoxical. The legislation that protects consumers established an apparently severe standard of strict liability for manufacturers. However, since it simultaneously introduces quantitative caps on this liability, the former criteria for malice and fault (whether or not they are derived from a criminal offence) would be applied in cases of harm that supercedes the liability caps. These criteria are based on the principle of complete compensation for harm and do not involve caps.

The previous argument suggests that we should maintain the standard of strict product liability for development risks, but adjust the liability cap to include possible massive damages.

As a result, frivolous claims of malice or negligence on the part of the defendant may be controlled by limiting the application of those rules to cases of intentional causation of harm or of clearly proven negligence.

With the introduction of Law 4/1999, the Government is released from all liability for development risks. If we take into account that the Health administration plays an active role in the regulation of the drug industry's activities and of the basic and applied research, then the exemption should be deemed remarkable. Particularly, if we consider that taxpayers are the ones held strictly liable because State employees may only be held liable for malice and gross negligence. Therefore, the Decision of May 31 of 1999, should not come as a surprise. It imposed a very difficult burden of proof to fulfill the requirements necessary to exclude the public administration from development risks. Similarly, the Penal Code's rules were extended in order to hold the State liable for the negligence of its employees. Once again, the colza case is a pertinent example.

It seems reasonable to suggest a unification and rationalization of liability standards. The unfortunate reform (art. 141.1 of Law 4/1999) of Law 30/1992 could be reversed. In particular, with regard to whether the public administration should take over the task of providing assistance to the victims of development risks. The State could provide funds for compensating victims and then recover the money by suing the tortfeasors, who would be liable along the line of the suggestions made in the previous paragraph.

- ***First Instance Court Decisions***

Case and Date	*Parties*
JPI num. 14 of Zaragoza, 16.2.1994	Joaquín O. v. «Laboratorios ICN-Hubber, S.A.»

- ***Court of Appeals' Decisions***

Chamber, Date and Court	*Catalogue*	*Judge*	*Parties*
1st, 17.1.1995, Zaragoza	original	José Javier Solchaga Loitegui	Joaquín O. v. «Laboratorios ICN-Hubber, S.A.»
1st, 4.4.1995, Baleares	Aran. 933	Julio López-Bermejo Muñoz	Widow of Nuria R. v. Antonio C., Melchor R., INSALUD and «Landerlan Laboratorios, S.A.»
1st, 24.4.1998, Barcelona	Aran. 829	María Nuria Zamora Pérez	Aurelia G., Sebastián C. and Mercedes C. v. «Hospital Cruz Roja Española» and «Quinta de Salud la Alianza»
1st, 24.2.1999, Alicante	Aran. 351	Manuel Benigno Flórez Menéndez	Aurora P. and others v. «Casa de Reposo and Sanatorio del Perpetuo Socorro, S.A.» and others

- ***Spanish Regional High Court Decisions***

Chamber, Date and Court	*Catalogue*	*Judge*	*Parties*
3rd, 17.3.1999, Madrid	Aran *on line* 391/6	Inés Huerta Garicano	Inheritors of Renate María K.K. v. Comunidad Autónoma de Madrid
4th, 9.6.1999, Navarra	El Derecho 16396	Carmen Arnedo Díez	Inés v. Servicio Navarro de Salud

- ***Spanish Supreme Court Decisions***

Chamber and Date	*Catalogue*	*Judge*	*Parties*
1st, 11.2.1998	Aran. 707	Antonio Gullón Ballesteros	Mª. del Pilar H. v. Leoncio M., INSALUD and Ministerio de

			Sanidad (health ministry)
1st, 28.12.1998	Aran. 10161	Ignacio Sierra Gil de la Cuesta	Mª. del Carmen M. v. Servicio Andaluz de Salud (Andalucian health service)
1st, 9.3.1999	Aran. 1368	Román García Varela	Isidoro M. v. INSALUD and Juan B.
1st, 5.10.1999	La Ley 2000, 916	Xavier O'Callaghan Muñoz	Joaquín O. v. «Laboratorios ICN-Hubber, S.A.»
1st, 10.11.1999	Aran *on line* 418/2	Ignacio Sierra Gil de la Cuesta	Widow and children of the deceased v. Servicio Andaluz de Salud
2nd, 26.9.1997	Aran. 6366	Gregorio García Ancos	Colza. Various plaintiffs v. Spanish State
3rd, 31.5.1999	Aran. 6154	Francisco González Navarro	Miguel Ángel L. v. INSALUD
4th, 5.5.1999	Aran. 4703	José María Marín Correa	Teresa R. P. and Sergio R. P. v. Servicio Valenciano de Salud